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CLINICAL AND SURGICAL ASPECTS OF TREATMENT OF DEGENERATIVE AND TRAUMATIC ROTATOR CUFF TEARS

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Clinical and surgical aspects of treatment of degenerative and traumatic rotator cuff tears
THESIS FOR DOCTORAL DEGREE (Ph.D.)

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To my late father who used to call me his very own scientist already when I was still a little girl. I am now officially a scientist. I hope you are pleased wherever you are.

Information is not enough. Neither is knowledge. We need wisdom.

The Character of the Aquarian Age

ABSTRACT

Pain caused by rotator cuff pathology or tear is a major source of discomfort and dysfunction in the shoulder joint. The prevalence of rotator cuff tear increases with age and also as the workforce becomes older. The number of otherwise healthy elderly individuals with high demands on functionality and quality of life in the society is also increasing. A successful rotator cuff repair leads to a good shoulder function, and excellent patient satisfaction however, the failure rate is still considerably high, especially in multi tendon and chronic tears in the elderly, despite the advances in surgical techniques. The overall aim of this thesis was to study factors, which might improve the result of surgical treatment.

Study 1) The purpose of this retrospective cohort study was to investigate the result of surgery after traumatic rotator cuff tear regarding the time delay to surgery after injury. Seventy-three patients (75 shoulders) were retrospectively examined with Magnetic Resonance Imaging (MRI) and functional outcomes at least one year after the surgery. The results were compared in patients who had surgery earlier or later than three months after their injury. No significant difference was found between the groups. The conclusion was that if repair was possible the timing should not impact surgical decision.

Study 2) The aim of this validation of outcomes instruments study was to validate the Swedish version of the Western Ontario Rotator Cuff index (WORC) in evaluation of treatment outcome for subacromial disease including rotator cuff tears. In total, 114 patients were included prospectively in this study. The WORC was tested against WOOS, Oxford Shoulder Score, Constant-Murley Score and EQ-5D. The results showed that the Swedish version of WORC was valid, reliable and responsive in evaluation of this group of patients.

Study 3) The purpose of this retrospective cohort study was to find factors on preoperative MRI prior to rotator cuff surgery, which might predict the outcome. In this study sixty-two pre- and postoperative MRI were compared. The results showed that preoperative tendon retraction of more than 40 mm, muscle atrophy according to Goutallier classification grade 3-4 might predict a worse surgical outcome, with a fivefold increase in the risk for a re-rupture. A prevention of progression of muscle atrophy and fatty degeneration was found in the successfully repaired shoulders but also an improvement in 8-11% of all the cases. This result favors surgery when a repair is technically possible.

Study 4) The aim of this prospective randomized controlled patient-blinded clinical trial with including fifty-eight patients was to investigate whether a synthetic patch might improve the result after rotator cuff surgery. In half of the cases the repair was augmented with a synthetic patch, Artelon®. Assessment was made by serial ultrasound during the first three months post-surgery. There were no differences identified in any of the outcome measures including functional scores and MRI at 12 months follow-up. Based on this result we would not recommend the routine use of a synthetic patch in cuff repair. However, the use of Artelon® was safe and leads to good function and patient satisfaction comparable to the conventional repair.

The results out of this thesis support the fact that the timing after traumatic rotator cuff tears is not a considerable factor in decision-making regarding surgical repair. The Swedish version of WORC is reliable and useful in assessing the outcome in subacromial disease including rotator cuff tears. There are findings on preoperative MRI that may predict the result of surgery in rotator cuff repair. The use of Artelon®, a synthetic patch augmentation, in rotator cuff repair is safe but not superior to traditional repair.

LIST OF SCIENTIFIC PAPERS

I. **Similar results comparing early and late surgery in open repair of traumatic rotator cuff tears**
Soheila Zhaeentan, Anders Von Heijne, Elisabet Hagert, André Stark, Björn Salomonsson, Knee Surg Sports Traumatology Arthrosc. 2015-Nov 12 (E-publication ahead of print)

II. **A validation of the Swedish version of the WORC index in the assessment of patients treated by surgery for subacromial disease including rotator cuff syndrome**
Soheila Zhaeentan, Markus Legeby, Susanne Ahlström, André Stark, Björn Salomonsson, BMC Musculuskeletal Disordorders, 2016 April, E-publication.

III. **Preoperative MRI-findings indicate the clinical outcome after rotator cuff surgery, a retrospective study of 62 patients**
Soheila Zhaeentan, Anders Von Heijne, Björn Salomonsson. Manuscript

IV. **Reinforcement with a synthetic patch in rotator cuff surgery fails to improve postoperative cuff integrity and clinical outcomes. A randomized patient blinded controlled study on 58 patients with 12 months follow-up**
Soheila Zhaeentan, Anders Von Heijne, Anders Elvin, Shwan Khoschnau, Hans Rahme, Björn Salomonsson, Manuscript

CONTENTS

LIST OF ABBREVIATIONS

ADL	Activities of Daily Living
CMC	Carpometacarpal joint
EMC	Extracellular Matrix
EQ-5D	European Quality of Life (EuroQol)- 5 Dimensions
GH	Glenohumeral joint
HRQoL	Health-Related Quality of Life
MCIC	Minimal clinically Important Change
MCID	Minimal clinically Important Difference
MID	Minimal Important Difference
mm	Millimeter
MRI	Magnetic Resonance Imaging
OBL	Oblique
OSS	Oxford Shoulder Score
PCC	Pearson Correlation Coefficient
PROM	Patient Reported Outcome Measures
QoL	Quality of Life
RC	Rotator Cuff
RCT	Rotator Cuff Tear
ROM	Range of Movement
SAG	Sagittal
SCC	Spearman Correlation Coefficient
TRCT	Traumatic Rotator Cuff Tear
VAS	Visual Analog Scale
WOOS	Western Ontario Osteoarthritis of the Shoulder index
WORC	Western Ontario Rotator Cuff index

1 INTRODUCTION

The earliest published description of a rotator cuff tear was by Alexander Munro II, the second of three generations of physicians and anatomists (figure1), when he described a **"Hole with ragged edges in the capsular ligament of the humerus"** in 1788 [33]**.** Since this description, 228 years have been passed but the exact indications for surgical repair of a torn rotator cuff are still subject to controversy among orthopaedic surgeons.

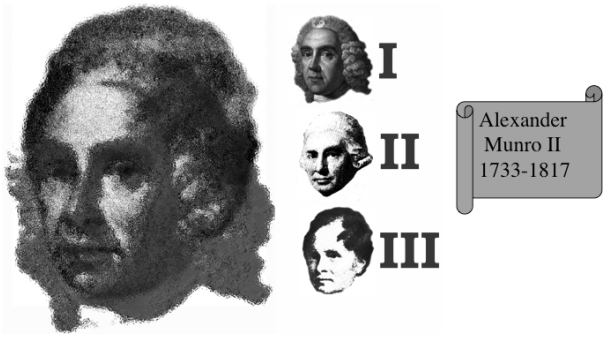


Figure 1: Alexander Munro II, the second of the three generations of anatomists, composed by Soheila Zhaeentan.

Almost five decades later in1834 Smith described the occurrence of tendon rupture after shoulder injury in the London Medical Gazette [136]. Codman carried out what may have been the first cuff repair in1909 and Meyer published his attrition theory of cuff rupture etiology in 1924 [21, 22].

Rotator cuff pathology and tear is a major source of suffering in individuals. It causes pain, dysfunction and lowers the quality of life. The prevalence of shoulder pain due to subacromial disease including rotator cuff tear increases with age and as the workforce becomes older. In a population-based study Yamamoto et al stated that the prevalence of rotator cuff tear was present in 20.7% of the general population and increased with age. While 36% of the subjects with current symptoms had rotator cuff tears, 16.9% of the subjects without symptoms also had rotator cuff tears [153]. Yamaguchi demonstrated that half of all asymptomatic rotator cuff tears become symptomatic within three years. Rotator cuff tears are common soft tissue injuries of the shoulder and affects 40% or more of patients aged older than 60 years [121].

The number of elderly that are physically active and less willing to accept functional limitation is also rising. However, these conditions are more likely to be overrepresented in individuals with occupations that include overuse activities of the arm above the shoulder level such as electricians, hairdressers and house painters or similar jobs. This leads to sick leave and great costs for society. According to the Swedish Social Insurance Agency the cost for diagnosis related till subacromial disease including rotator cuff tear was calculated as being nearly one billion SEK in 2009 [158] yet the cost for employers who account for the first two weeks of leave is not included in this figure nor is the human suffering that is incalculable in such terms.

In the past decades the amount of performed surgery on patients with a rotator cuff tear has been increased dramatically. In the United Kingdom with 10.000 surgeries annually by 500% [50] and in the United States by 230% from 75,000 rotator cuff surgeries in 2007 [147] to 250,000 annually in 2013 [84]. Mather et al showed in their study that the estimated lifetime societal savings of the approximately 250,000 rotator cuff repairs performed in the United States each year was USD 3.44 billion. Societal savings were highly sensitive to age, and savings were found to be positive at the age of sixty-one years and younger. However, the age-weighted mean total societal savings from rotator cuff repair compared with non-operative treatment was USD 13.771 over a patient's lifetime. They concluded that rotator cuff repair is cost-effective for all populations and the results showed that rotator cuff repair plays an important role in minimizing the societal burden of rotator cuff disease [84]. Nevertheless, despite the advances in surgical techniques still the recurrent rate is still too high.

The inspiration for this thesis originated from experiences during my specialty training when I came into contact with patients with symptomatic rotator cuff tear who were denied surgery due to age or since the torn tendons were considered too chronic to repair. I learned eventually what a positive impact a successful repair has on function, satisfaction and quality of life. The disappointment was however the high failure rate in the tendon healing.

2 BACKGROUND

2.1 ANATOMY OF THE ROTATOR CUFF

The rotator cuff (RC) comprises a group of tendons and muscles in the shoulder, connecting the upper arm (humerus) to the shoulder blade (scapula). The rotator cuff tendons provide stability to the shoulder and the muscles allow the shoulder to rotate in different directions. The muscles in the rotator cuff include: M. Supraspinatus, M. Infraspinatus, M. Subscapularis and M. Teres minor. Each muscle of the rotator cuff originates at the scapula, and has a tendon insertion that attaches to the greater or lesser tubercle of the humeral head. The tendinous portions of these muscles form the rotator cuff. The subacromial structures consist of the rotator cuff, the long head of the biceps and the subacromial bursa.

The **Supraspinatus** muscle is active in any movement involving elevation of the arm and plays an important role in glenohumeral (GH) joint stability. On account of its anatomical position above the humeral head and beneath the acromion, the supraspinatus is exposed to compression and attrition, which might explain the fact that the supraspinatus is the most commonly torn tendon of the RC [102]. The supraspinatus muscle is innervated by the suprascapular nerve, a mixed motor (musculus supra- and infraspinatus) and sensory (sensory innervation of the posterior-superior aspect of the shoulder) nerve and it arises from the upper trunk of the brachial plexus. A common cause of the suprascapular nerve entrapment is increased tension on the nerve from retracted RC tears. Suprascapular neuropathy should be suspected when a patient presents with posterosuperior shoulder pain, atrophy or weakness of supraspinatus and infraspinatus without RC tear, or massive RC tear with traction [9, 133]. Vascularity is provided from branches of the thoracoacromial artery and the suprascapular artery, however the tendon is poorly vascularized near its insertion site. Furthermore, the tissue 1.5 cm from the edge of a tear consists of poor viability, meaning that it is essentially not viable and would not heal. This may help to explain the high rate of re-rupture seen in larger tears [85].

The **Infraspinatus** muscle covers the area below the spine of the scapula (infraspinatus fossa) and inserts at the posterior aspect of the greater tuberosity of the humerus. It acts as the main external rotator of the humerus and it also contributes to depressing and stabilizing the humeral head in the GH-joint.

The **Subscapularis** muscle covers the inside of the scapular blade and inserts at the lesser tuberosity of the humeral head. It is the largest and most powerful of the RC muscles and acts as the primary internal rotator of the humerus as well as stabilizer of the humeral head in the glenoid cavity.

The Teres minor is also an external rotator of the humerus and assists the other RC muscles in stabilizing the GH-joint. Figure 2 demonstrates the normal anatomy of the RC at a front and back view. Figure 3 shows a ruptured supraspinatus tendon.

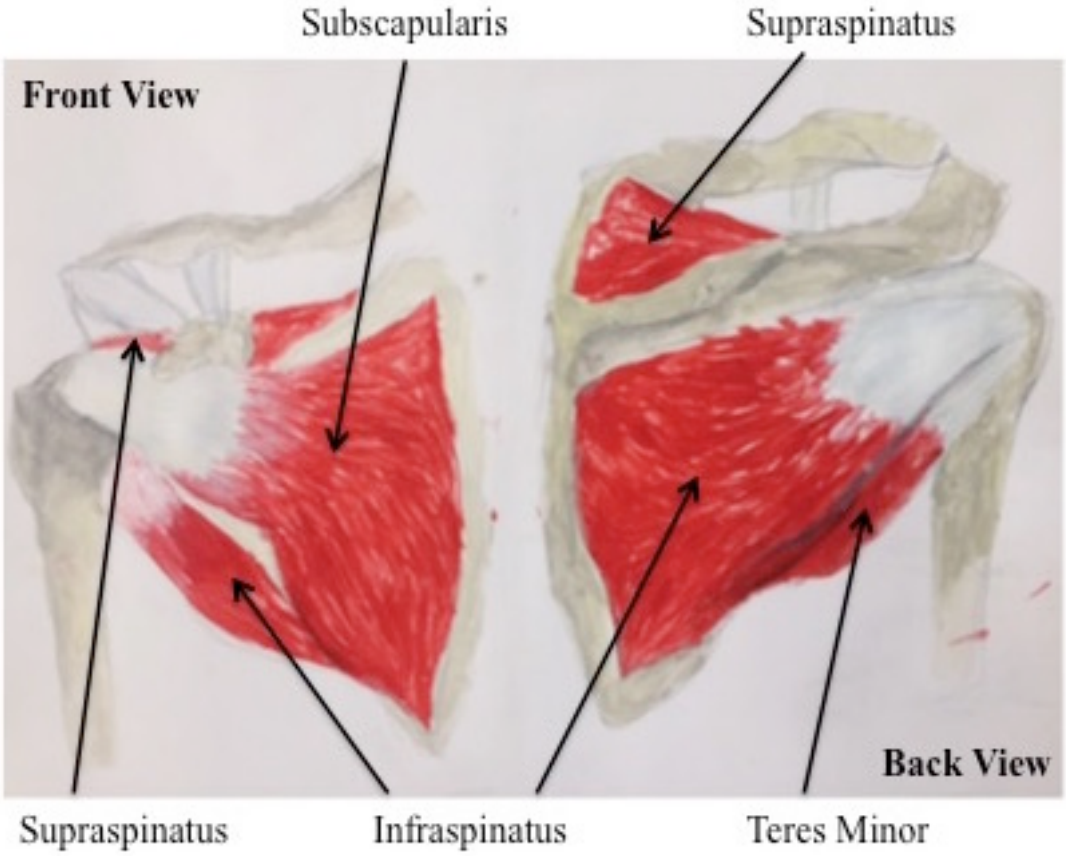


Figure 2: Normal anatomy of the rotator cuff muscles. Illustration by Chanelle Scheffer.

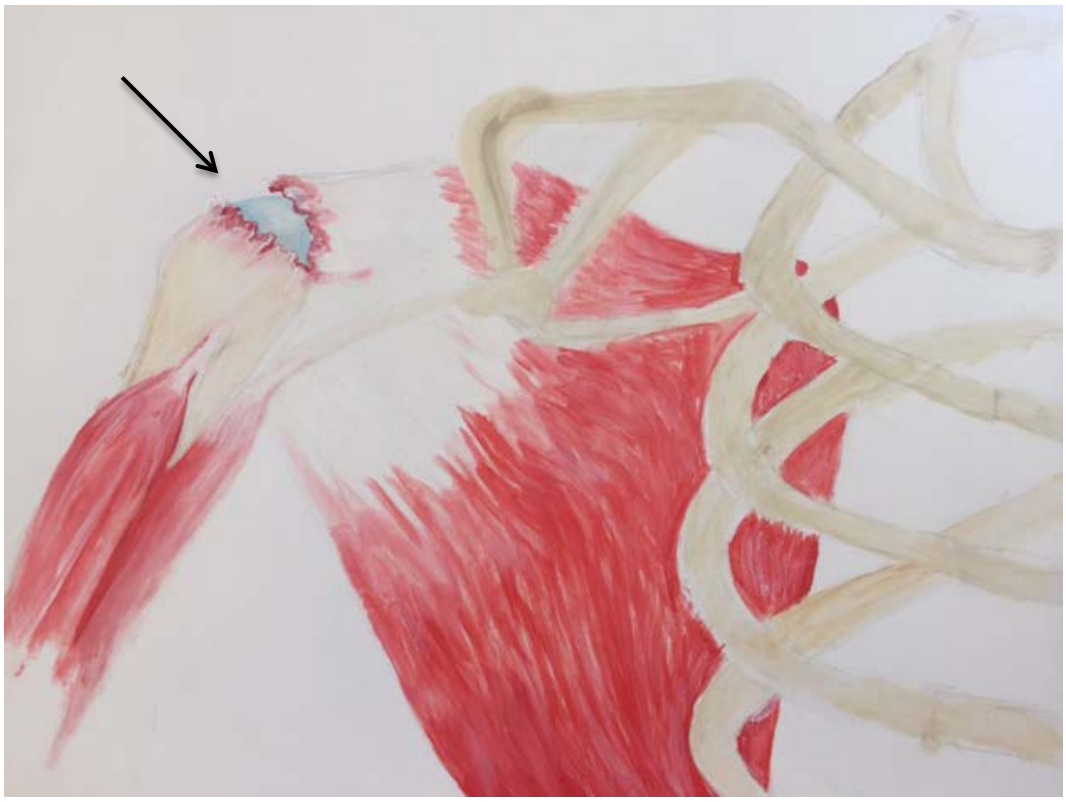


Figure 3: Rotator cuff tear. Illustration by Chanelle Scheffer.

2.2 ETIOLOGY OF ROTATOR CUFF TEAR

The etiology of subacromial impingement and rotator cuff tear is multifactorial. A combination of traumatic, mechanical, circulatory and degenerative factors is probably involved [40, 106]. Factors, which were most important for rotator cuff tears, were discussed already in the 1930s [23, 90]. Several authors have studied the circulation of the supraspinatus tendon and found reduced circulation in the tendon just before the attachment site on the greater tuberosity [96, 126]. In the recent years new studies have supported the theory proposed by Codman [23], that intrinsic tendon degeneration was a major factor in tears of the RC. Matthews et al. showed in 2007 that also the cellular activity was decreased in full-thickness tears of the RC as the size of the tear increased which may explain the high rate of the re-ruptures seen in larger tears[85].

Charles Neer found after extensive studies of cadavers, in the beginning of the 1970s, that impingement occurs toward the front acromion, coracoacromiale ligament and acromioclavicular joint [103]. He divided the impingement into three stages of inflammation, fibrosis through to the last stage of burdening bone and tendon ruptures. Neer [102] believed that 95 percent of cuff tears were caused by impingement under the coracoacromial arch that forms the roof of the shoulder joint demonstrated on an x-ray image of a normal shoulder, figure 4. Björnsson et al. showed in a study in 2010 that arthroscopic subacromial decompression seemed to reduce the prevalence of RC tears in impingent patients [7]. On the other hand Ogata and Uhthoff considered (1990) that RC tears were rather developed as an intrinsic degenerative tendinopathy [107]. Some individuals are considered predisposed to suffering depending on the architecture of the acromion [4, 5, 95, 100] and exposure to heavy repetitive work [53]. Traumatic rupture occurs frequently from fall against the outstretched arm in an individual with a degeneratively weakened cuff, although the individual may have been free of symptoms before the injury. Even secondary forms of impingement occur, for example, in younger subjects with unstable shoulders and in peritendinitis calcarera. Internal impingement is a particular ailment particularly seen in throwing athletes [87].

Figure 4: Shows a frontal view of a normal right shoulder of a 61-year old woman. Photo courtesy of Anders Elvin.

2.3 PATHOLOGY OF ROTATOR CUFF TEAR

The pathogenesis of RC tears is unclear, however the condition is considered to be a combination of extrinsic impingement from structures surrounding the cuff [5] and intrinsic degeneration from changes within the tendon itself [92, 107, 132, 144].

A full-thickness rotator cuff tear is a defect in the tendon that reaches from the bursal to the articular margin [11]. Typically, these tears occur at the footprint of the greater tuberosity where the tendon fibers insert, and then propagate proximally. Full-thickness rotator cuff tears are quantified as small (<1 cm), medium (1-3 cm), large (3-5 cm) and massive (>5 cm) according to the DeOrio and Cofield classification, as measured in their longest dimension [29].

Rotator cuff pathology is a common shoulder disorder experienced in the orthopaedic patient population. The spectrum of these disorders ranges from inflammation to massive tearing of the rotator cuff musculotendinous unit. A combination of synovial inflammation and tendon degeneration might lead to progress in tear disease [134].

2.4 DEGENERATIVE VS TRAUMATIC ROTATOR CUFF TEAR

RC tear is proven to be a degenerative process, a part of aging and increases significantly with age [132, 144]. Distinguishing between an acute tear and a chronic degenerative tear

with acute deterioration is difficult [39, 74, 137]. Adequately distinguishing between an acute tear and an existing chronic tear with an acute onset of symptoms after trauma remains challenging since asymptomatic rotator cuff tears exist [132, 144].

2.5 TREATMENT

Rotator cuff tears can be treated both surgically and non-surgically with improved outcome [130]. Repair of a torn RC has been shown to give predictable pain relief and functional improvement, with good overall patient satisfaction [109]. Traumatic tears are uncommon: most patients present through an age-related degeneration of the tendon attachment to bone at the proximal humerus [153]. Surgical repair may be considered for patients with persistent symptoms who fail to respond to rest and conservative care [16].

The treatment recommendation that symptomatic full-thickness rotator cuff tears should be treated surgically is considered to be based on expert opinion with weak level of evidence [115]. Massive rotator cuff tears are associated with persistent defects, weakness, and poor outcome. A recurrent rate higher than 50% can be expected when more than one tendon is torn, especially in elderly, although an intact repair resulted in good function and patient satisfaction compared to shoulders with a non-intact repair [52].

Treatment options [129]:

- Non-operative options (injection and/or exercise)
- Debridement/partial repair
- Acromioplasty and biceps tenotomy/tenodisis
- Repair (open/mini open or arthroscopic)
- Reconstruction (muscle transfer or processed tissue)
- Arthroplasty (reverse shoulder prothesis)

Non-operative option (also known as conservative treatment) includes rest, corticosteroid injections, and physiotherapy. Surgical treatment is included debridement with or without a partial repair when the size of the tear is to large to be repaired completely however also this procedures might restore functional use of the shoulder [12, 45, 104]. An acromioplasty or subacromial decompression that it is also called and biceps related procedures are explained in section 5.2. A complete repair of a RC tear is desirable and it can be done through an open or an arthroscopic approach. The advantages and disadvantages of each technique are outlined in table 1 [149].

Reconstruction with muscle tendon transferring, such as latissimus dorsi, is an alternative to produce a stable shoulder kinematic and provide symptomatic relief in irreparable massive rotator tendon tear with weakness [41, 42]. This method is best adopted for patients younger than 60 years of age. For the older patients who have also developed arthritis on the other hand, a reversed total joint arthroplasty is the only and last surgical option, figures 5 and 6.

The advantages and disadvantages of each treatment are outlined in table 2 [149].

Table 1: Demonstrates advantages and disadvantages with different surgical techniques in RC repair, source https://www.shoulderdoc.co.uk/education/arthrosc_v_mini_open_rcr.htm.

Techniques	Advantages	Disadvantages
Open	Easy to do Inexpensive No special equipment required Allows direct visualization of cuff repair and acromioplasty Good long-term follow-up.	Deltoid detachment required, increased perioperative morbidity in all comparative studies reported (Baker and Liu, Weber) Patients with false positive studies or irreparable tear will be opened Significant intraarticular pathology will be missed except in very large tears
Arthroscopic	Patients like it "sell surgery" Avoid opening patients with false positive studies or irreparable tear Diagnosis and arthroscopic treatment of intraarticular pathology	Patients like it "sell surgery" Requires arthroscopic skills Costs
Mini open with/without arthroscopic aid	Appears to combine advantages of open repair (direct visualization of repair, palpation of acromioplasty, long-term success of repair) with arthroscopic visualization and decreased morbidity.	

Table 2: Procedures, advantages, and disadvantages of various surgical treatment modalities for rotator cuff disease

Surgical procedures	**Advantages**	**Disadvantages**
Rotator cuff repair	Favorable long-term outcome Restores normal anatomy Pain relief Theoretically, protective against further degenerative changes in muscle and tendon	Long recovery Tendon healing unpredictable
Debridement/biceps tenotomy/acromioplasty	Indicated primarily for irreparable tear Pain relief Lower morbidity than muscle transfer or arthroplasty	Less predictable results Further degenerative changes to bone and soft tissue structures possible
Muscle transfer	Salvage procedure for irreparable cuff Potentially restores strength Pain relief	Limited indications Mixed results Long recovery period
Reverse shoulder arthroplatsy	Salvage procedure for irreparable tear Pain relief Restores function	Higher morbidity and complication rate Limited indications, that is, older patients

Killian et al 2012, table reproduced with permission from publisher.

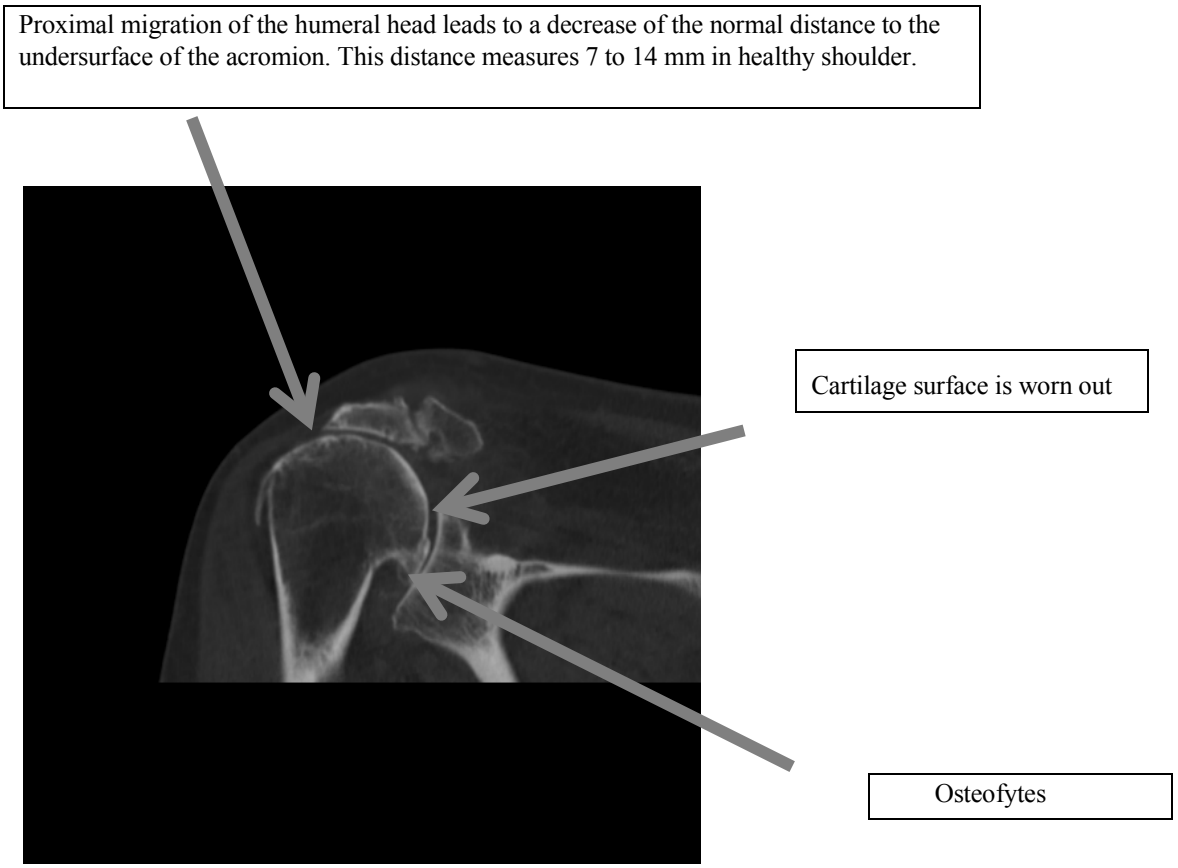


Figure 5: Demonstrates a computer tomographic view of the right shoulder, 80-year-old man, with a severe arthritis due to chronic massive rotator cuff tear, photo courtesy of Björn Salomonsson.

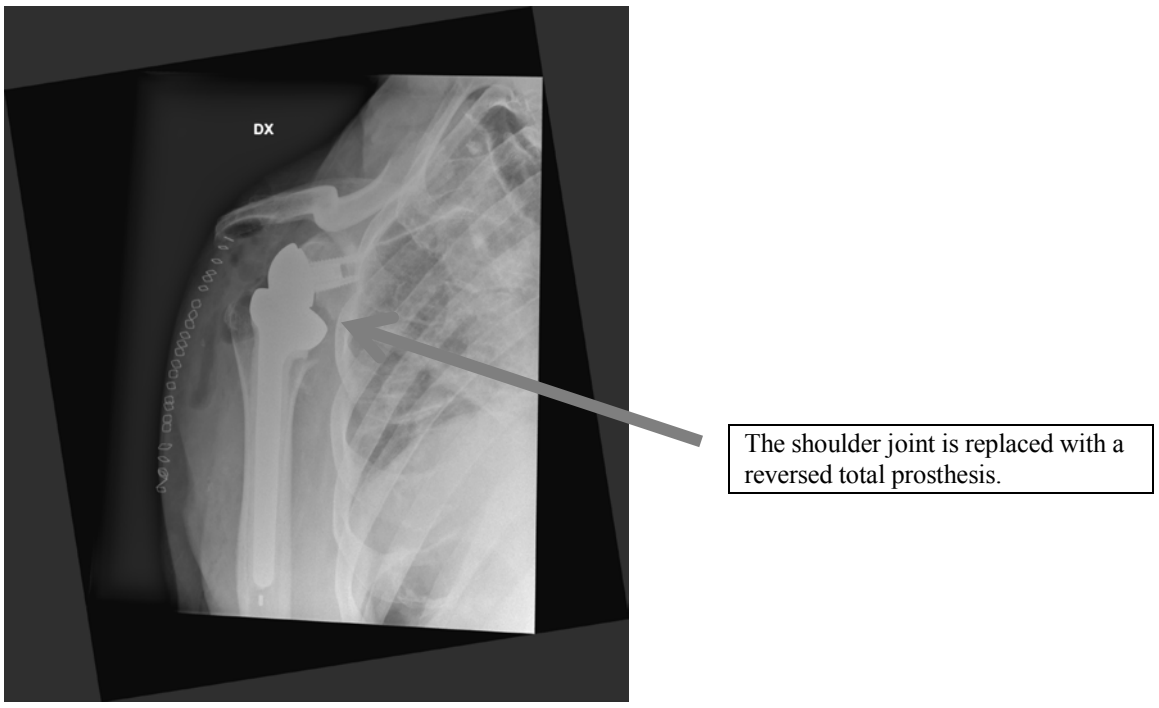


Figure 6: Demonstrates x-ray view of the same shoulder after reversed shoulder arthroplasty surgery a few months later, photo courtesy of Björn Salomonsson.

3 AIMS OF THE THESIS

The overall aim of this thesis was to study indications for surgical treatment of symptomatic degenerative and traumatic rotator cuff tears and also factors that might lead to improvement of the results.

The specific aims were:

Study I The aim of this retrospective comparative analysis was to investigate whether the timing of surgery after a traumatic rotator cuff tear (TRCT) with acute symptoms affects the functional outcome and patient satisfaction in the long-term.

Study II To assess the validity, reliability, and responsiveness of the Swedish version of the WORC score in the evaluation of subacromial disease including rotator cuff tear in patients treated by surgery.

Study III To investigate whether there were findings on the preoperative MRI that could predict the postoperative results and clinical outcomes after rotator cuff surgery.

Study IV The aim of this randomized controlled patient blinded study was to investigate whether the use of a synthetic patch, Artelon®Tissue Reinforcement, in rotator cuff surgery may result in a better clinical outcome and decrease postoperative failure rate compared to repair without augmentation.

4 ETHICAL CONSIDERATIONS

All the patients were able to understand written and spoken Swedish. Written informed consent was obtained after the patients had been given verbal and written information about the study before the inclusion (study I, III, IV). All these studies were performed with the approval of the Regional Ethical Review Board at Karolinska Institutet, Stockholm, Sweden; Dnr 2010/1965-31/3 (study I+III) and Dnr 2011/1059-32/2 (study IV). In study II approval by the Regional Ethical Review Board was obtained, Dnr 2006/54-31/2. All the participants in this study approved participation through signing the self-evaluating functional scores used in the study.

5 METHODOLOGICAL CONSIDERATIONS

5.1 PATIENTS

All the patients participating in the studies were recruited at Aleris Specialistvård, and Danderyd Hospital in Stockholm and the Elisabeth Hospital in Uppsala. The patients are generally referred by a general practitioner to these settings for a specialist review due to persistent shoulder pain and failure to respond to conservative treatment. Study subjects were recruited from the bulk of visiting patients with diagnosed rotator cuff tears candidate for surgery. In total 196 patients have been involved in this thesis; however, some of these patients were included in more than one study. Forty-nine patients from study I participated in the test-retest of the WORC score in study II and sixty-two preoperative MRI from patients in study I were analyzed in study III.

Patients in study I

The study period was January 1999 to December 2011. We included retrospectively 73 patients (75 shoulders) who were surgically treated for TRCT and met the inclusions criteria for this study, figure 7. The inclusion criteria were as follows: 1) patients who had undergone surgical repair of full-thickness rotator cuff tear; 2) 18 years of age or older at the time of surgery; 3) and a known history of trauma prior to the onset of symptoms. Exclusion criteria were: 1) a concomitant fracture or dislocation; 2) and/or TRCT that had been left without surgical repair. The study cohort was divided into two treatment groups for comparison. Those who had undergone repair <12 weeks from injury (39 shoulders) were placed in an early group and those who had undergone late repair ≥12 weeks after the injury (36 shoulders) in a late group. The patients were 58 men and 17 women. The mean age at surgery was 59 years for both groups, range 34–72 in early and range 42-72 in late group.

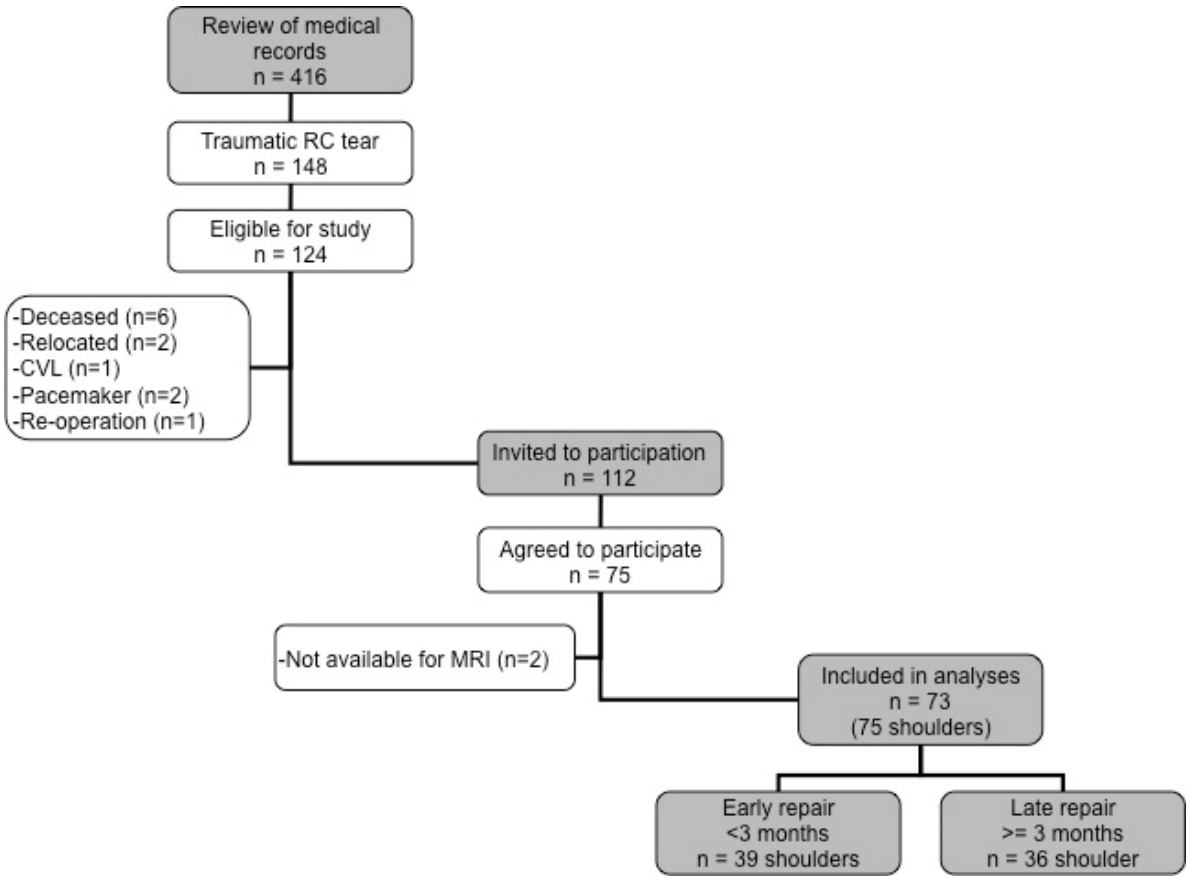


Figure 7: Flowchart for inclusion and exclusion in the study I. Reproduced with permission from the publisher.

Patients in study II

This study consisted of two groups of patients: either as a pre- and postoperative group (group 1) or as test-retest group (group 2). The patients in group 1 were recruited from routine patients at one orthopaedic department in 2004-2006 (47 patients) and at another orthopaedic unit during 2011-2012 (18 patients). The patients were eligible to participate if diagnosed with a subacromial disease including impingement, biceps tendonitis or rotator cuff tears or a combination of these, were candidates for surgery and agreed to participate. The mean age of the patients was 60 years (range 36-82 years), and 27 (42%) were women.

Group 2 consisted of a total of 49 patients, who answered the WORC twice, in a test-retest manner. These 49 patients were retrieved from study I. the mean age of the participants was 64 years (range 36-74 years) and 10 (20%) of them were women.

Patients in study III

The inclusions criteria in this study were 1) previous surgery for rotator cuff tear; 2) both pre- and postoperative MRI available; and 3) and an existing informed consent.

The cohort for this study was obtained from patient material included in study I. The material in study I consisted of 73 patients (75 shoulders) who had undergone open surgery for TRCT during 1999-2011 and had done a postoperative MRI at follow-up. The mean time from operation to follow-up was 56 months (range 14-149). These patients were selected for that study due to the fact that there was a known history of trauma prior to the onset of symptom. Sixty-two of these patients with available preoperative MRI could be included in this study. The mean age was 60 years (range 34-72), 23% female, and mean time from injury to surgery was 16 weeks (3-104).

Patients in study IV

The study period was from February 2012 until April 2015. Inclusion in this study was performed in a consecutive manner as and when patients were allocated for surgery. All the patients who had a one- to two-tendon full thickness RCT aged 35-80 were eligible for inclusion. We chose to use the Boileau classification [10] for tear size and patients with tear stage II and III in sector B-C or D, alone or in combinations, were included, see appendix. In this study, 58 patients were included, mean age 62 (range 39-77), 32 men (55.2%) and 26 women (44.8%). In total 29 patients were randomized to repair with patch augmentation and 29 without. Both traumatic and degenerative tears were included. A traumatic tear was defined when a force or injury was present prior to the onset of symptoms and a degenerative tear when symptoms existed with the absence of a known onset factor. The consort randomization flow diagram is demonstrated in figure 8.

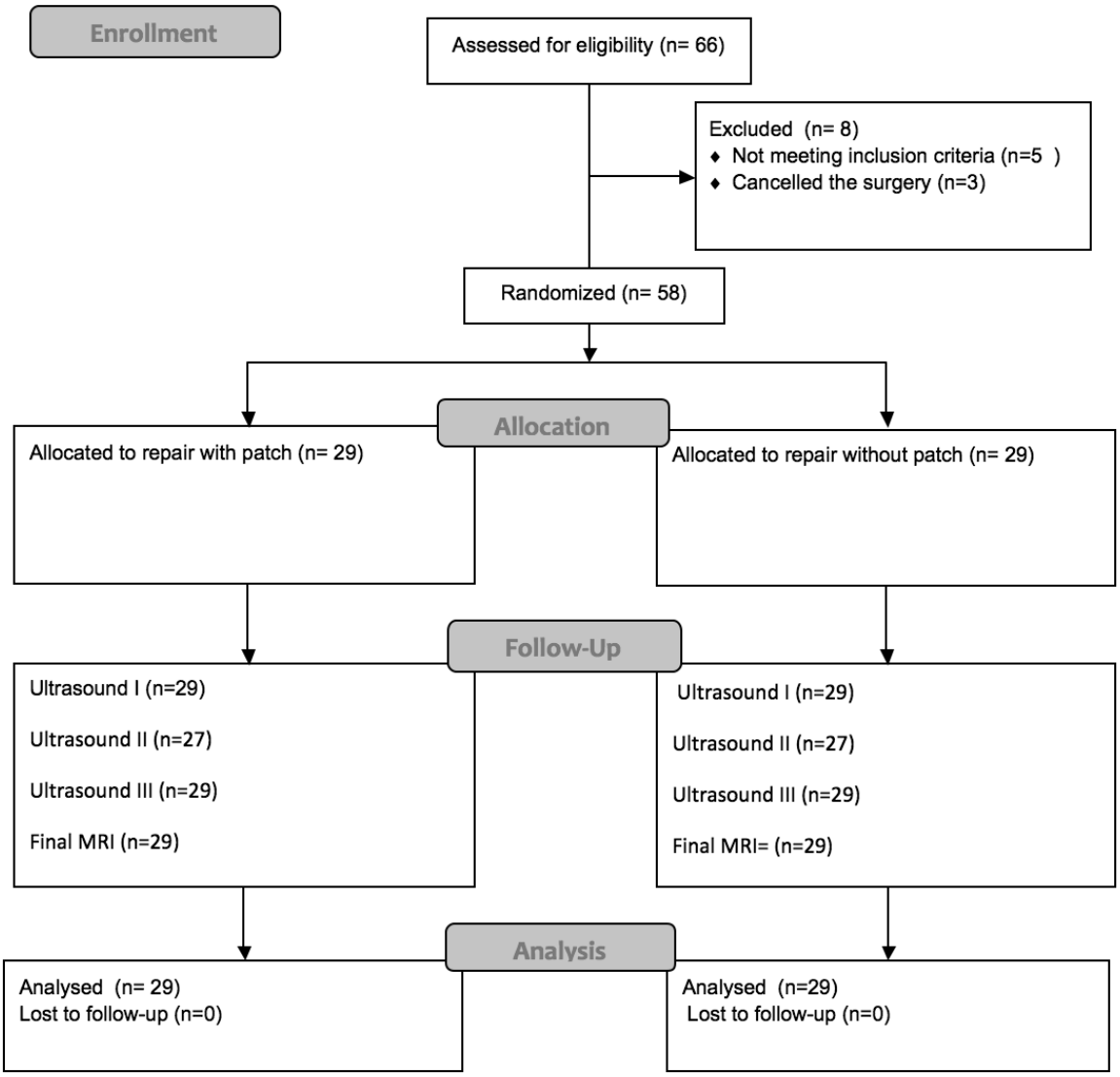


Figure 8: Consort flow chart for study IV.

5.2 SURGICAL METHODS

In total 18 patients in study II, and 32 patients in study IV were operated by Soheila Zhaeentan.

A rotator cuff repair operation aims to re-attach the tendons to the bone. The repair may also include bursectomy, acromioplasty and biceps tenodesis or tenotomy.

In general, two approaches are available for surgical repair [16]:

- **Open/mini-open** surgery involves the rotator cuff being repaired under direct vision through an incision in the skin.
- **Arthroscopic** surgery involves the repair being performed through arthroscopic portals.

In the study IV the patients were operated with both the open and arthroscopic based on the surgeons' preferences. In total four surgeons contributed. A brief description of the procedure used is outlined below:

Both open and arthroscopic surgery was performed in general anesthesia, and with a diagnostic arthroscopy prior to the repair. Some patients received an interscalene block prior to general anesthesia. An examination under anesthesia was performed regarding motion and instability. The arthroscope was introduced into the GH joint through a standard posterior portal and the joint was inspected for any concomitant pathology. The cuff tear was inspected from the inside and the reparability of tear was assessed.

Arthroscopic Technique

Patients were placed in the beach chair position with the arm suspended in a simple traction device using 3-4 kilogram of traction. The cuff tear inspected from the inside and after that the arthroscope was introduced into the subacromial space. The bursa was partially removed and if necessary an acromioplasty was performed in all cases. Pathology of the long head of the biceps was addressed by a tenodesis or as in the majority of the cases, with a tenotomy. The cuff tear was mobilized without any attempts to perform extensive tendon release, and repaired with two to four suture anchors (Helix, J&J) depending on the size of the cuff tear. Single or double row repair was used depending of what was most appropriate according to the judgment of the surgeon. Portals were closed with interrupted sutures (Etilon Eticon), then covered with sterile dressings and followed by application of an abduction brace.

Open technique

Patients were placed in the beach chair position, and after initial arthroscopy underwent open surgery according to the technique described by Neer [101]. The bursa was partially removed and if necessary an acromioplasty was performed. Pathology of the long head of the biceps was addressed by a tenodesis, or as in the majority of the cases with a tenotomy. The torn rotator cuff was mobilized back to its insertion at the greater tuberosity. The repair was performed with suture anchors (Twinfix 5.0 mm; Smith&Nephews Inc., Memphis, TN, USA or Corkscrew® Anchors 5.5 mm, Arthrex Inc, Naples,Fl, USA) attached into the greater tuberosity. Single or double row repair was used depending of what was most appropriate by the judgment of the surgeon.

Once the rotator cuff repair was completed, open or arthroscopically, the patients were randomized to augmentation or not. The patch was then applied if indicated, and the wound was closed.

Augmentation process

If the patch was used, it was soaked with sterile saline at room temperature for approximately 5 minutes and then cut and shaped to fit over the repair, figure 9. The edge was rounded to make smooth corners. In open surgery the patch was sutured in place with six to eight PDS sutures. One of the sutures was placed in the center of the patch to press it tightly to the bursal side of the repaired tendon and prevent bulging, figure 9.

For arthroscopic application the patch was rolled up and introduced through the lateral portal into the subacromial space. The patch was spread out over the repair by traction in the four corner sutures and sutured to the repaired cuff with a shuttle device, using six to eight PDS sutures.

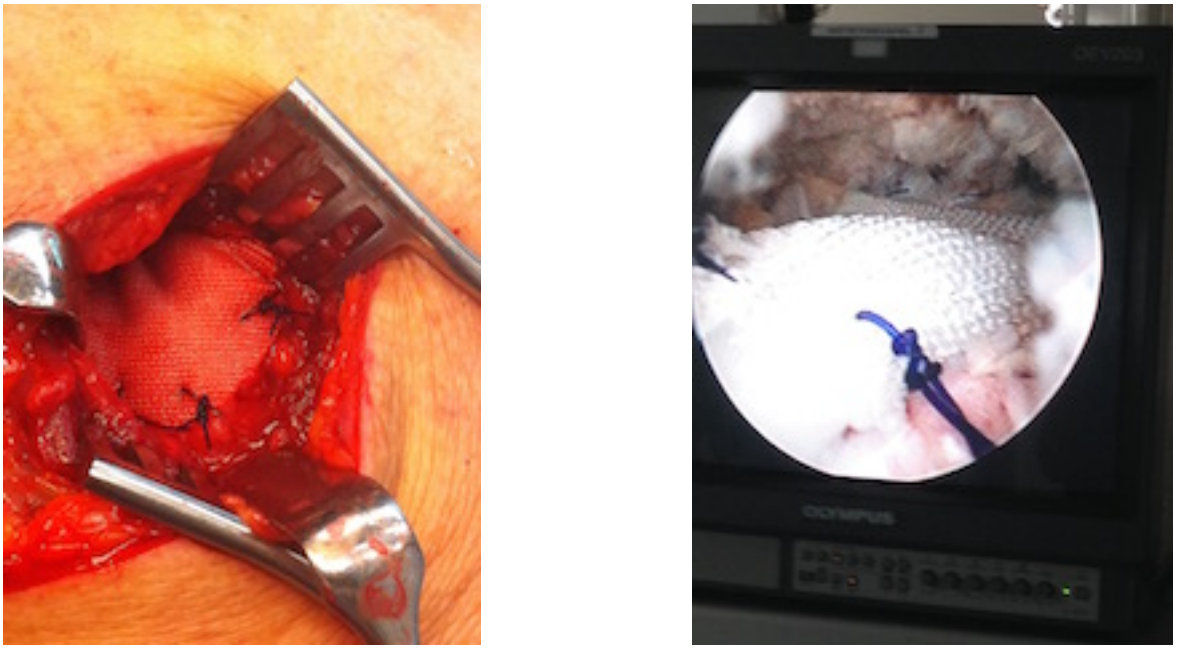


Figure 9: Open repair of torn rotator cuff. The cuff is covered with Artelon® Tissue Reinforcement after complete repair (left picture) and arthroscopic repair of torn rotator cuff with Artelon® Tissue Reinforcement after complete repair (right). Photo: Soheila Zhaeentan.

Additional per-operatively procedures:

- **Bursectomy**

  The inflamed and hypertrophic subacromial/subdeltoid bursa debrides through an open or arthroscopic approach. This action always accompanies an RC repair for better visualization.

- **Subacromial decompression, acromioplasty**

  Excision of the overhang of bone and soft tissue above the RC at the inferior anterolateral aspect of the acromion with the aim of creating more space for the rotator cuff tendons to move freely. Neer first described this open procedure in 1972 [103] and the arthroscopic technique was first described by Ellman in 1987 [34].

- **Bicep tenodesis/ biceps tenotomy**

  If the long head of the biceps tendon is found to be degenerative and inflamed it can be treated either through a tenodesis which involves detaching the long head of the biceps tendon from the superior labrum in the shoulder and reattaching it to the humeral bone just below the shoulder joint or through a tenotomy in which the long head of biceps tendon is released from it's attachment in the shoulder joint, allowing it to fall down into the upper arm and out of the shoulder joint. This removes the damaged, inflamed tissue by releasing it from the joint.

Postoperative regime

In all the operated patients, regardless of the surgical techniques, the arm was immobilized in a sling for approximately 6 weeks, with passive physiotherapy training of the arm commencing three weeks postoperatively. Active range of motion was recommended after removal of the sling. Formal cuff strengthening was delayed until 12 weeks postoperatively.

5.3 SYNTHETIC PATCH AUGMENTATION

Due to the well-known high rate of failed RC repair and recurrence rate, especially in elderly and when more than one tendon is torn [52] the interest for augmentation has risen in order to improve the result of rotator cuff surgery. There have been several scaffolds developed to augment the repair, however the evidence existing in the literature in this field is currently insufficient. Neviaser was the first to report the use of a scaffold device, a freeze-dried graft from cadaveric RC, to augment a repair in the late 1970s [105]. In 1986, Ozaki et al. reported the use of polyester as well as polytetraflouroethylene (Teflon) grafts to repair massive RC tears [111]. Both reported good tolerance and improved functionality in non-controlled case series. Currently, there are three types of augmentation commercially available, the biologic patches (extracellular matrix-based, ECM) that include allograft and xenograft, the synthetic grafts and hybrid scaffolds that are a combination of ECM-based and synthetic materials [121]. A recently published systematic review article has thoroughly evaluated the effectiveness of grafts in the augmentation of large-to-massive rotator cuff repairs [36]. The xenograft augmentation has been shown to have lower structural healing rates than conventional repairs, as well as resulting in severe inflammatory reactions [118, 148]. Iannotti et al [56] in a RCT stated that using xenograft (Restore ®) from porcine small intestine submucosa as augmentation of the surgical repair of large and massive chronic rotator cuff tears did not improve the rate of tendon-healing or the clinical outcome scores. On the other hand there is one randomized controlled trial [1] and three observational studies that support the use of human dermal allograft as an augmentation device for the repair of

large-to-massive rotator cuff tears. Also the synthetic patches group has shown initially promising results [20]. There are a few synthetic grafts using different material currently available, however, research in this field is also limited. There are a few published case series in respect to Artelon® Tissue Reinforcement which is used in Study IV, and they have shown promising results on function and patients satisfaction but there is a lack of control groups [83, 156]. The clinical effectiveness of synthetic patches has yet to be proven and well conducted clinical trials are urgently required [50]. The synthetic graft used in this thesis (study IV) is a knitted fabric made from Artelon® fibers which are a degradable polyuretanurea (Artimplant AB, Gothenburg, Sweden, it has also been distributed as SportsMesh Soft Tissue Reinforcement, Biomet, Indiana, US). The Artelon® implant is biocompatible, degrades slowly and maintains its strength and elasticity over several years, providing long-term support of the soft tissue at the same time as comprising a scaffold for host tissue ingrowths [43]. Artelon® can be used in surgical procedures for the reinforcement of soft tissue where weakness exists, figure 10.

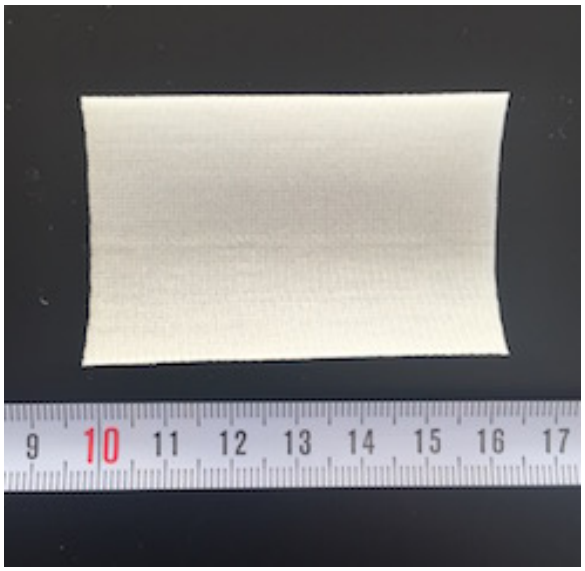


Figure 10: The Artelon® Tissue Reinforcement patch which can easily be cut and shaped to fit over the repaired rotator cuff, photo: Soheila Zhaeentan.

5.4 RANDOMIZATION PROCESS

During surgery, after the torn rotator cuff had been completely repaired, the patients in study IV were randomized to treatment either for augmentation with Artelon® reinforcement or without augmentation. Patients were enrolled consecutively and assigned to the intervention prior to the surgery and a randomization envelope was opened only when the torn rotator cuff was successfully repaired to secure the randomization process. The randomization was arranged by an independent statistician, and consecutively numbered and sealed in opaque envelopes. The randomization envelopes were handed over to each hospital as a block of ten. When a hospital had consumed all the ten randomizations envelopes it received another block of ten. One hospital included 32 patients (randomization no. 1-10, 31-40, 41-50 and 71-72), one hospital 9 patients (randomization no.11-19) and the third hospital 17 patients (randomization no. 21-29 and 51-58). Randomization no. 20 was never used and no. 30 was lost.

5.5 IMAGING MODALITIES

Magnetic Resonance Imaging (Study I, III, IV)

In total 247 MRI investigations have been assessed in this thesis.

Conventional radiographs constitute a simple and available method of investigation for patients with a painful shoulder and are often used to supplement a clinical examination, however the method rarely has a place in rotator cuff diagnostics. Contrarily MRI has been shown to be an excellent and reliable tool for diagnosis of the soft tissue pathology in the shoulder region. Ianotti el al. demonstrated in 1991 that MRI has 100% sensitivity and 95% specificity in the diagnosis of complete tears, and that it consistently predicted the size of the tear of the RC [57]. MRI has since in several studies been shown to be an excellent non-invasive tool in the diagnosis of lesions of the RC [35, 110, 155, 157]. However, MRI is expensive, time-consuming, and probably not widely available.

In study I all the patients (73 individuals, 75 shoulders) underwent MRI of the operated shoulder according to a standardized image series at the follow-up. A senior radiologist, blinded to the patients outcome and study group (early, versus late, surgery), assessed all the MRI images. In study III, 62 preoperative MRIs from the study I cohort were compared to follow-up MRI in order to delineate factors that might predict the surgical outcome. In this study the retraction of the supraspinatus tendon was measured as the maximum distance from the most lateral portion of the footprint on the greater tuberosity to the torn tendon edge on T2-weighted oblique coronal images, in this study.

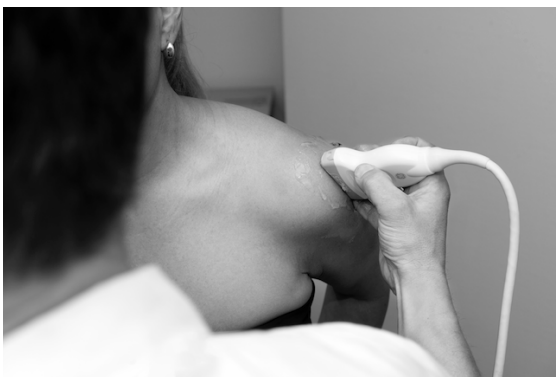
In Study IV, 52 preoperative MRI were assessed in comparison to follow-up MRI between the two surgery groups, RC repair with and without synthetic patch augmentation.

Ultrasound (Study IV)

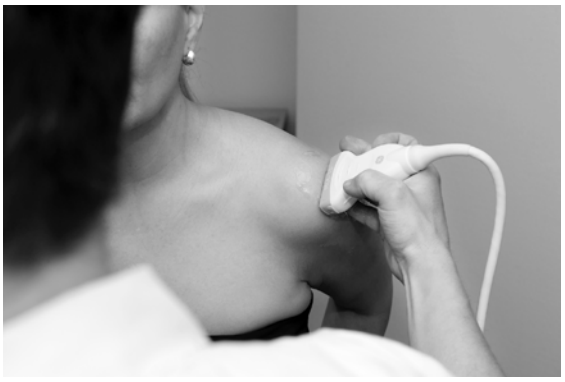
In total 170 ultrasound investigations have been assessed in this thesis.

Ultrasound imaging techniques have been available for clinical use since the 1970s. The first article in regard to the use of ultrasound in the diagnosis of RC pathology was published in 1979 [131]. However, the application of this technique in the field of musculoskeletal diagnosis has become popular in the recent years especially in the patients with suspected cuff disease. Advances in recent decades in ultrasound technology and the development of high-resolution ultrasound transducers have enabled detailed depiction of superficial musculoskeletal structures. While considered in the past as complementary to MRI, ultrasound has clearly become competitive [120]. Ultrasound is now the imaging modality of choice for evaluating tendon pathology. Several studies are available reporting high sensitivity, specificity, and accuracy, up to 96%, for diagnosing full- and partial-thickness tears [60, 94, 142, 143]. Ultrasound can be used to accurately diagnose and quantify full- and partial-thickness tears and recurrent tears in the postoperative shoulder, determine the tear

location, and evaluate the cuff muscles for fatty degeneration. It can also be used to diagnose other cuff disorders such as tendinopathy and calcific tendinitis and non-cuff pathology of the biceps tendon, acromioclavicular joint, posterior labrum (paralabral cyst), and sub-deltoid bursa [141]. A meta-analysis by de Jesus et al. showed that MRI and ultrasound were comparable in both sensitivity and specificity for diagnosing full- and partial-thickness cuff tears [60]. It is important to accurately diagnose and characterize cuff tears for treatment planning. Ultrasound findings help the orthopaedic surgeons decide whether treatment should be surgical or nonsurgical. Recently, the acceptance of shoulder ultrasound by orthopaedic surgeons has become increasingly popular as an office-based investigations tool. Ultrasound is less expensive and allows for dynamic evaluation, as well as being less demanding for the patient than MRI. Ultrasound offers focused examination with rapid, real-time diagnosis, side-to-side comparison, and treatment in desired clinical situations. In experienced hands it takes no more than a couple of minutes as part of a routine clinical assessment of the RC integrity. Murphy et al. stated that the predictive values obtained for the evaluation of RC integrity were comparable with published results from experienced radiologists and the capacity of their proposed learning protocol to train surgeons without previous ultrasound experience to reliably evaluate RC integrity using ultrasound within fifty to hundred scans [98]. In a PhD thesis, Sunding demonstrated recently the value of the use and accuracy of ultrasound as a tool for diagnostics, treatment guidance and evaluation of treatment results in regard to some of the most common musculoskeletal overuse-injures and pain disorders at an orthopaedic outpatient clinic [63]. Figure 11 demonstrates positioning of the transducer for viewing supra- and infraspinatus.



Positioning of the transducer for longitudinal view of the rotator cuff (supra- and infraspinatus).



Positioning of the transducer for transversal view of the rotator cuff (supra- and infraspinatus).

Figure 11: Ultrasound examination of the supra- and infraspinatus in left shoulder. Photo: Johan Adelgren**.**

5.6 FUNCTIONAL OUTCOME SCORES

In total 1391 scores have been analyzed in this thesis.

Constant-Murley Score (Study I-IV)

In total 319 CS scores have been assessed and calculated in this thesis.

Constant-Murley Score (CS) is a shoulder-specific score, developed by Constant and Murely in 1987 [27] and later modified by him and his co-workers in 2008 [26]. CS was one of the first shoulder scores, however it was not evaluated until 2010 by Roy et al. who stated excellent responsiveness while some properties still needed to be further evaluated, particularly those related to the absolute errors of measurement and Minimal Clinically Important Difference (MCID) [127]. CS is scored from 0 (minimum/worst) to 100 (maximum/best) of which 35 points are dedicated to subjective (patient-determined) assessment of pain and ADL and 65 points are dedicated to objective (observer-dependent) measurements of movement and strength. This 100-point scoring system is divided into 4 subscales: pain, 15 points; activities of daily living (ADL), 20; range of motion (ROM), 40; and strength, 25. CS is currently one of the most frequently used tools for evaluating shoulder function and is recommended in shoulder research by the European Society of Shoulder and Elbow Surgeons (SECEC) [61, 66]. However, the CS requirement of objective measurements has even been criticized for having low inter-rater reliability [25, 26, 125]. This makes the CS less appropriate when comparing outcomes between different shoulder-treatment centers. In contrast, the WORC has been constructed for use in multicenter studies and for use in postoperative follow-ups [65].

In this thesis we used Isobex® isometric dynamometer (VERIBOR, Germany) in study I and II, and IDO-ISOMETER (Innovative Design Orthopaedics, Redditch, UK) [70] in study IV for isometric abduction strength measurement with patients in sitting position with the arm in the scapular plane and 90°, figures 12 and 13.

Figure 12: Demonstrates the Isobex dynamometer device measuring isometric abduction strength in elevation in the plane of the scapula, photo courtesy of Susanne Ahlström.

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Figure 13: Demonstrates the IDO-ISOMETER device measuring isometric abduction strength in elevation in the plane of the scapula, photo: Soheila Zhaeentan.

EQ-5D Score

In total 316 scores have been assessed and calculated in this thesis.

The EQ-5D questionnaire, the health status component of the Euro-Qol assessment (EuroQol Group, Rotterdam, The Netherlands) [159], is a generic, self-reported non-disease-specific instrument, for describing and evaluating health-related quality of life. European Quality of Life- 5 Dimensions 3 L (EQ-5D) is the most commonly used generic questionnaire for assessment of QoL in Sweden and has thoroughly been used in this thesis. However, the other main HRQoL generic instrument used in orthopaedics, Short Form 36 (SF-36), is the most widely used health-related quality-of-life measure in research to date [75].

The health status is divided into five dimensions (morbidity, self-care, usual activities, pain/discomfort and anxiety/ depression), each within three severity levels (no problems, moderate problems and severe problems). In this thesis we used the British tariff for the total index, which has been shown to be valid for the Swedish population [15], for calculation of our patients EQ-5D results. The EQ-5D also includes a vertical VAS scale ranging from 0 worst possible health status) to 100 (best possible health status). The EuroQol instrument has been designed for self-completion and it takes a couple of minutes to complete. It aims to capture physical, mental and social functioning, and is intended to be applicable over a wide range of health interventions. The EuroQol group acknowledges its simplicity and recommends that it should be used together with other instruments. The reliability and validity of the EQ-5D has been evaluated in different patient populations including the Swedish population.

Oxford Shoulder Score (OSS)

In total 205 OSS scores have been assessed and calculated in this thesis.

The validated, patient-reported Oxford Shoulder Score (OSS) was developed by Dowson et al. in 1996 primarily for the assessment of outcomes of shoulder surgery (excluding shoulder stabilization) in randomized trials [28]. It has gradually been adopted as an outcome measure and is now widely used in clinical studies and has been translated into and validated in several languages. The OSS relies on the patient's subjective assessment of pain and ADL impairment and has been shown to correlate well with both the Constant Score and the SF36 assessment and to be sensitive to surgical intervention. The OSS is a 12-item questionnaire for completion by patients. With 5 possible answers to each item, it accumulates to a total score with a maximum value of 60 points (5x12) when each answer gives one point. Another option is to calculate answers to a maximum of 48 (4x12) when the first question which indicate normal status gives zero points. In this thesis we have used the latter option. The total score of the OSS includes four pain-related, 33%, whilst the remaining 67% is derived from eight ADL-related questions. Previously the highest scores reflected the worst outcomes in the OSS, however this was modified by developers in 2009 and was inverted so that a higher score could correlates with a better outcome in order to match more conventional "worse-is-lower" methods [28].

Western Ontario Osteoarthritis of the Shoulder Index (Study II)

In total 130 WOOS scores have been assessed and calculated in this thesis.

The Western Ontario Osteoarthritis of the Shoulder Index (WOOS), a disease-specific and patients-administered quality of life measurement questionnaire for osteoarthritis of the shoulders, was originally developed by the Canadian research group in 2001 [79]. An approved translation of the WORC into Swedish was used for the purpose of the study II. The Swedish version of WOOS was validated in patients with subacromial pain by Klintberg et al. in 2012 [67]. The questionnaire consists of 19 items, each with an analogue response option (0-100 mm). The items cover 4 domains: 6 questions for pain and physical symptoms, 5 questions for sport/recreation/work, 5 questions for lifestyle function and 3 questions for emotional function. The total score can range from 0 (i.e. best or asymptomatic) to 1900 (i.e. worst or most symptomatic). To present the result in a more clinically meaningful way Lo et al. [79] suggested reporting the raw score by the percentage of normal shoulder function in clinical studies. WOOS and WORC are quite similar to each other except that the WORC includes 21 questions, 5 domains, and has separate domains for recreation/sport and work.

Western Ontario Rotator Cuff Index (Study I-IV)

The WORC has been used at primary outcome in study I, III and IV and the Swedish version of WORC has been validated in study II. In total 421 WORC scores have been assessed and calculated in this thesis.

The Western Ontario Rotator Cuff Index (WORC), see appendix, a disease-specific quality of life measurement tool for validation of rotator cuff disease, was originally introduced and published by Kirkley et al. in 2003 [65]. It was developed as a response to the lack of well-constructed instruments for measuring QoL in patients with rotator cuff syndrome. The original version of the WORC was created in English, and the psychometric evaluation that was made can therefore be considered valid only in that language [49]. Since 2003, the WORC has been translated into and psychometrically evaluated in at least nine languages [32, 55, 62, 82, 150].

The WORC comprises 21 items that address symptoms in five domains; physical symptoms - 6 items, sport/recreation - 4 items, work - 4 items, lifestyle - 4 items, and emotions - 3 items. Each item's response is presented on a visual analogue scale of 0-100, where 0 represents the least amount of symptoms and 100 represents the worst symptoms. The results can be calculated for each separate domain, as well as providing a total score ranging from 0 (least symptoms) to 2100 (worst symptoms). The total score can be recalculated to represent a percentage of a healthy shoulder, with 100% being the best score depicting a healthy shoulder. Recalculation is performed using the formula (2100 – "patient WORC score"/21). Psychometric properties of the Swedish version of the WORC for assessment of subacromial disease including rotator cuff syndrome treated by surgery have been validated in the study II.

6 STATISTICAL METHODS

The descriptive statistics and statistical analyses were conducted using SPSS, version 21.0 or version 22.0 (SPSS Inc., Chicago, Illinois, US). All variables were summarized using standard descriptive statistics such as frequencies, means and standard deviations.

Study I

For a comparison between the two groups, representing early (<3 months) and late surgical repair (≥ 3 months) surgical repair, the Mann-Whitney U-test was used for continuous variables. The Fisher's exact test for dichotomous variables, and the Mantel-Haenszel chi-square test was used for the ordered categorical variables. We added 95% confidence intervals (CI) for the continuous variables. The statistical analyses were based on the patient as a unit that is, only the data from one operated shoulder was used in the analyses of the two patients who had both shoulders operated on for a rotator cuff tear. All significance tests were two-sided and conducted at the $p<0.05$ level of significance. The statistical models were chosen in collaboration with a statistician.

Study II

The following methodology was applied in the individual statistical tests:

The co-variance of the instruments was calculated using the Pearson's correlation coefficient (PCC) or the Spearman correlation coefficient (SCC). The SSC is a non-parametric alternative to the PCC. The PCC was calculated using the pre- and postoperative material from group 1 for correlation assessment and was calculated individually for the scores WORC, WOOS, OSS, and EQ-5D. The SCC was calculated for the correlation between satisfaction level (SL) and the WORC's total score. Furthermore, the PCC was calculated with respect to test and retest WORC scores. The correlation with the test-retest material could then be compared to the correlation calculated between WORC and WOOS scores. Sample size recommendation for validation studies indicates that approximately 50 patients would be required in this study.

Study III

The Mann-Whitney U test was used for comparisons of unpaired groups for the continuous variables that were not normally distributed according to Shapiro-Wilks test. For the categorical data the Chi-Square and Fisher exact test were used to compare frequencies in two different groups. The level of significance was set at $p < 0.05$. All statistical analyses were performed using SPSS version 22.0.

Study IV

The Mann-Whitney U-test was used to establish the difference in continuous variables between the groups that were not normally distributed according to Shapiro-Wilks test,. For categorical data Chi-square and Fisher exact tests were used to compare frequencies in two different groups. For differences between baseline data and final measurements Wilcoxon Signed Rank test was used, $p< 0.05$ was considered statistically significant.

7 RESULTS

Study I

No differences were found between the early- and the late-surgery groups in any of the outcomes measured (table 3). The WORC also showed similar results between the two groups in all the five domains as well (figure 14). There were no differences in re-rupture frequency; 18 shoulders (24%) were found to have a re-tear in the repaired rotator cuff, nine in each group. Additionally, no differences in the results were observed in the male and female patients.

Table 3: Outcome measure by scores at follow-up in the two groups, early and late surgical repair.

	<3 months *n* = 39 Mean (SD), range	≥3 months *n* = 36 Mean (SD), range	Difference between groups p-value
WORC score (%)	77 (22), 25-100	77 (22), 27-100	0.86
Constant score (points)	68 (22), 17-98	69 (22), 6-98	0.91
Oxford score (points)	41 (8), 18-48	41 (8), 13-48	0.79
EQ-5D index	0.82 (0.18), 0.24-1	0.83 (0.19), 0.29-1	0.86
EQ-5D VAS	82 (15), 35-100	79 (18), 30-100	0.35

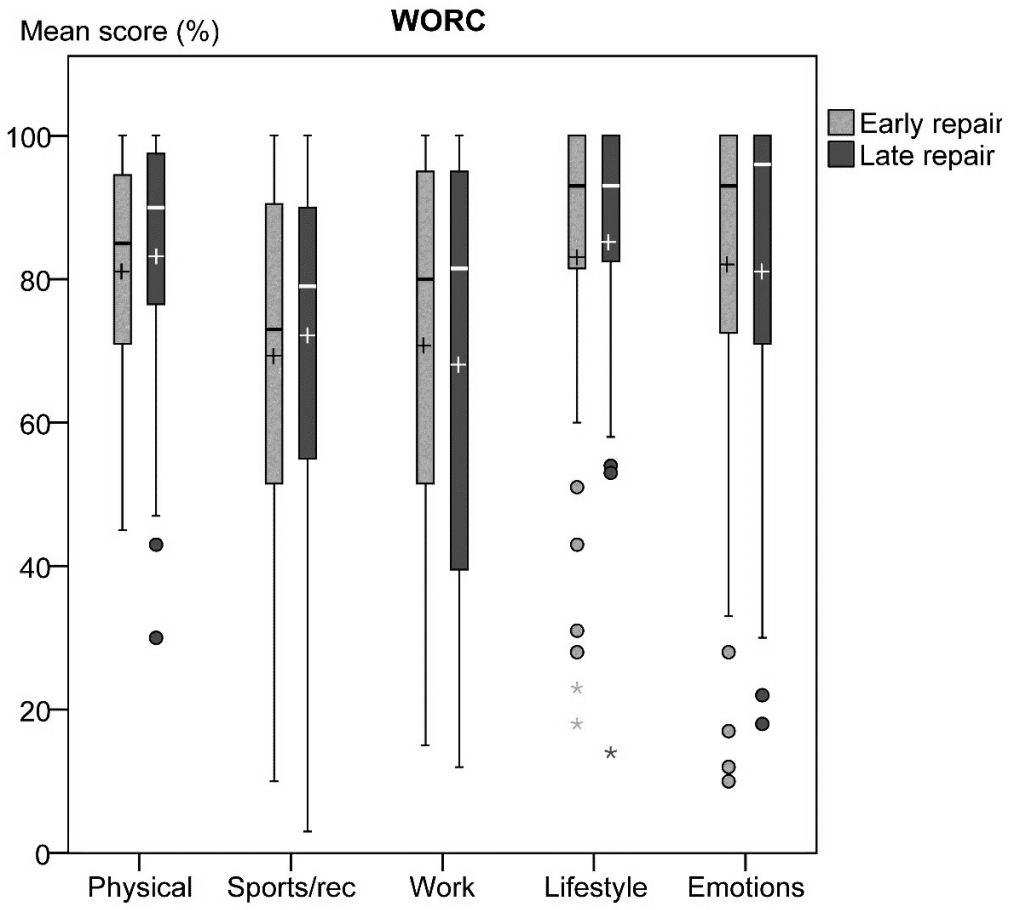

Figure 14: The result for the five WORC-domains in early and late surgery groups.

However, there were statistically significant differences in all measured scores between the patients with intact cuff repairs and those whose cuff repairs were not longer intact (Table 4)

Table 4: The results for patients with intact and non-intact cuff repair on MRI at follow-up. WORC score (0-100%), Constant score (0-100 points), Oxford Shoulder Score (0-48 points).

	Intact repair	**Non-intact repair**	**Difference**
	n = 57	*n* = 18	p-value
	Mean (SD), range	Mean (SD), range	
WORC Score	81 (20), 25-100	63 (22), 27-99	0.002
Constant Score	74 (18), 17-98	51 (23), 6-82	<0.001
Oxford Shoulder Score	42 (7), 18-48	38 (9), 13-48	0.023

Figure 15 demonstrates the tendon involvement for the two surgery groups.

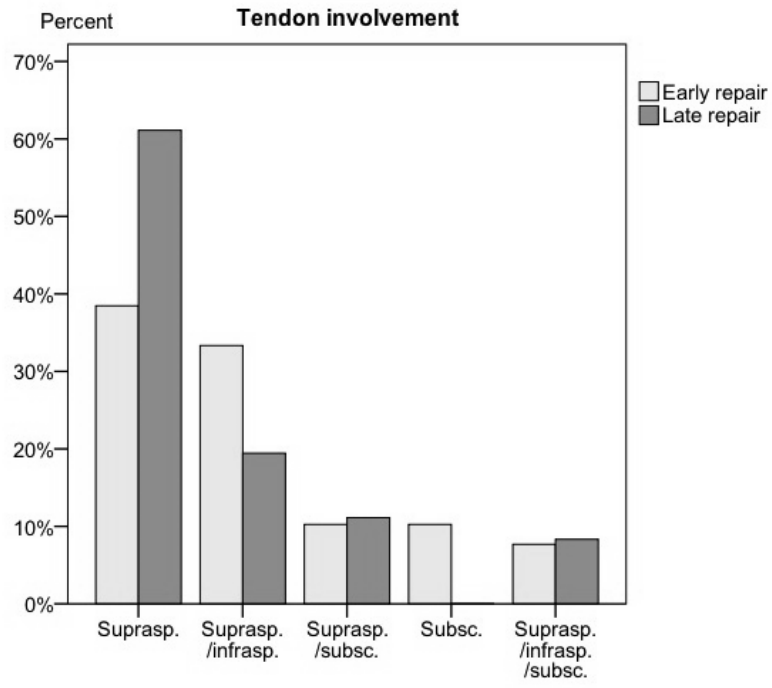

Figure 15: Demonstrates involvement of the tendon lesions in the two groups, early and late repair at the time of surgery.

Study II

The results of this study suggest that the Swedish version of the WORC is indeed valid, reliable, and responsive enough to be used in the evaluation of the QoL in patients with sub-acromial disease including rotator cuff tears treated by surgery. The validity analysis of WORC showed high correlations with both the specific and the generic health measurement instrument (WOOS, CS, OSS and EQ-5D). The construct validity (Pearson's correlation coefficient) was 0.97 between WORC and WOOS, figure 16. Chronbach's alpha (internal consistency) was high with 0.93 preoperatively and 0.98 postoperatively. Responsiveness was also excellent for WORC with Effect size = 1.35 and Standardized Response mean = 1.01. We also found strong content validity of 0.97 between WORC and WOOS which might raise the question as to whether there is a need for both of the scores. The suggestion from this study would be to choose either the WORC or WOOS since both are validated for use on patients with subacromial pain. However, the WORC might possibly have a higher validity or responsiveness among a working population than the WOOS since that domain is slightly more extensive in WORC. It may also be more likely the case that patients with subacromial and rotator cuff disease are to be found among working age patients than patients who suffer from arthritis.

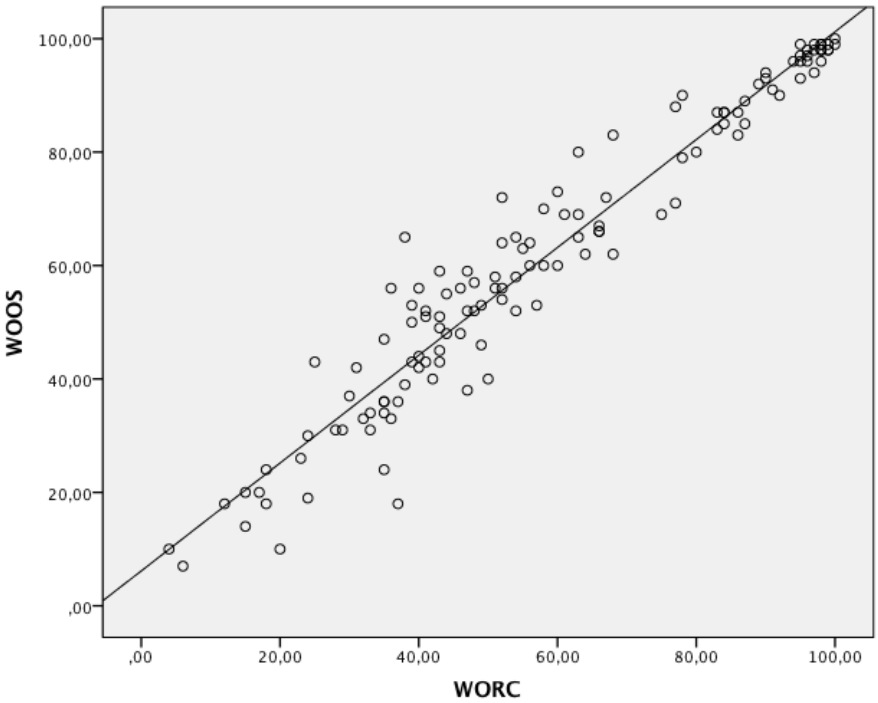

Figure 16: Scatter plot of WORC total scores vs. WOOS total scores**.** The results for the WORC and the WOOS of 64 participants, both pre- and postoperatively (N=128). PCC was 0.97 between WORC and WOOS. Abbreviations: WORC = Western Ontario Rotator Cuff index, WOOS = Western Ontario Osteoarthritis of the Shoulder index, PCC = Pearson's correlation coefficient.

The test-retest reliability of the WORC was strong (ICC = 0.97), and the separate domains also showed a high ICC, ranging from 0.84 to 0.98, figure 17.

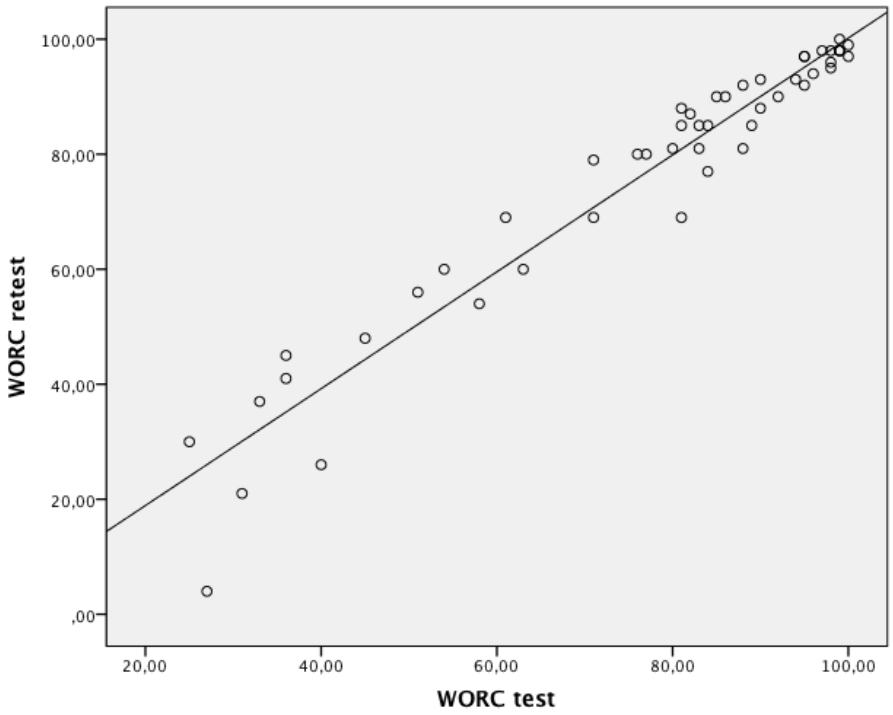

Figure 17: Scatter plot of WORC test vs. WORC retest. The individual results of the WORC test material plotted against the individual results of the WORC retest material (n = 49).

Study III

This retrospective comparative study, comparing MRI preoperatively and at follow-up showed that a preoperative tendon retraction >40 mm was related to a five times higher re-rupture risk as compared to 40 mm or less of retraction table 5. Re-rupture frequency was 26% (16/62) with average WORC 63% and CS 51 points, as compared to 81% and 74 points for intact repairs (p=0.001 and p<0.001, respectively). There was a high rate of unchanged muscles (50% Thomazeau grading and 61% Goutallier), with improvement of these measures in 11% and 8% respectively, figure 18. No differences in these outcomes were found between the age groups (≤ 60 and >60 years).

Table 5: Re-rupture rate and the association to the preoperatively tendon retraction.

Tendon retraction pre-op	n	Re-rupture frequency	p-value
0-40 mm	49	7 (14%)	
>40 mm	13	9 (69%)	<0.001
Total	62	16 (26%)	

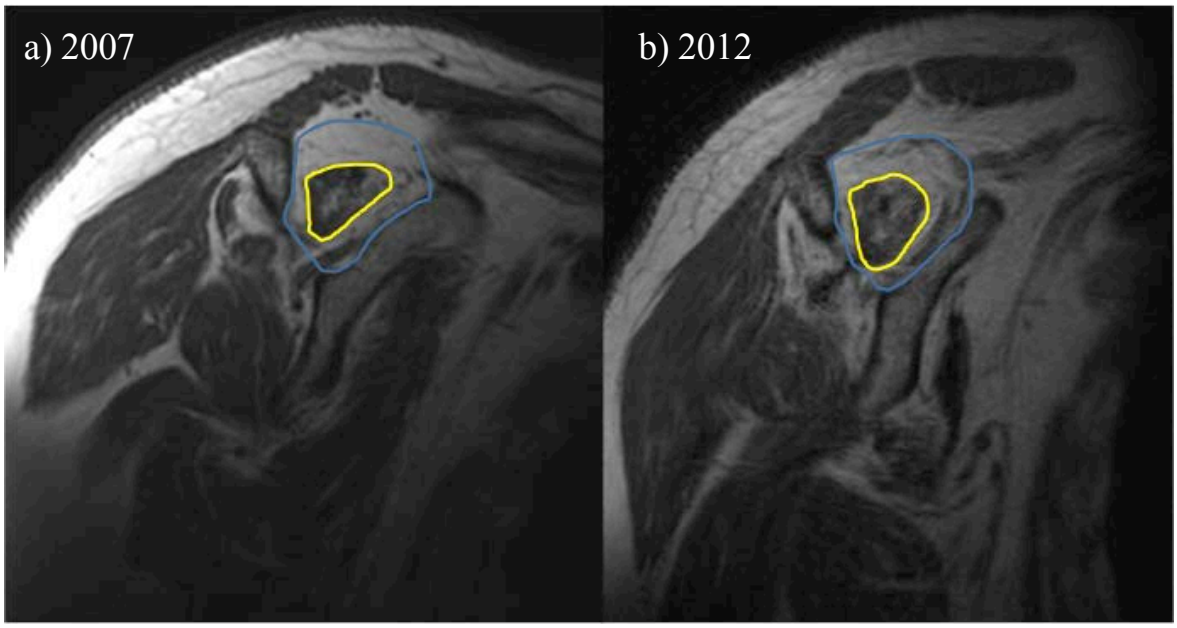

Figure 18: Demonstration of the measurement of the occupational ratio for supraspinatus muscle in a torn rotator cuff in the supraspinatus fossa on MRI before and five years after a successful repair in the same shoulder. S1 (yellow) / S2 (blue), (OBL SAG PD).

a) Preoperative right shoulder with a Supraspinatus rupture, age 63, in 2007.

b) Five years after surgery with a successful repair, in 2012.

The example shows a significant improvement with regard to both the muscle atrophy and fatty degeneration: Thomazeau grading improved from stage 3 to 2, Occupation Ratio R: 1a) 0.30 and 1b) 0.46 and Goutallier staging from stage 3 to 1. Photo courtesy of Anders von Heijne.

Study IV

This prospective, randomized and patients blinded study comprised 58 patients, with one- to two-tendon full-thickness rotator cuff tear, who underwent repair with, or without, augmentation with Artelon® Tissue Reinforcement. In all, 29 patients were randomized in each surgery groups, baseline characteristics for the groups are outlined in table 6. We could conclude that Artelon® could successfully be used, was safe and resulted in an improvement of the postoperative outcome and patient satisfaction. However, augmentation with Artelon®) showed no superiority to conventional rotator cuff repair. Based on the results of this study, the use of Artelon® could not be recommended routinely in this group of patients. No significant difference was found between the groups in all the clinical outcomes measured, i.e. the WORC, CS and EQ-5D as well as the cuff repairs integrity with a 26% re-rupture rate at 12-month follow-up. No serious adverse incidences were observed postoperatively during the follow-up period. However we diagnosed four patients with a postoperative frozen shoulder of which three were in the patch group and one in the control group. The follow-up consisted of serial ultrasound at 4, 8 and 12 weeks postoperatively and MRI at 12-month, the results are demonstrated in table 7. There was missing data on ultrasound at 8 weeks for four patients, two in each group, due to holiday season in summer. However all of these four patients where shown to have intact cuff integrity at the 12-week follow-up.

Table 6: Baseline characteristics for the two study groups, repair with synthetic patch and the control group.

	Synthetic patch n = 29	**Control group** n = 29	**Total** n = 58
Age at surgery, mean (SD) range	64 (7) 48-77	60 (9) 39-73	62 (8) 39-77
Sex, n (%)			
Female	10 (34.5%)	16 (55.2%)	26 (44.8%)
Male	19 (65.5%)	13 (44.8%)	32 (55.2%)
Surgery side, n (%)			
Right	21 (72.4%)	18 (62.1%)	39 (67.2%)
Left	8 (27.6%)	11 (37.9%)	19 (32.8%)
Dominant hand, n (%)			
Right	26 (89.7%)	26 (89.7%)	52 (89.7%)
Left	3 (10.3%)	3 (10.3%)	6 (10.3%)
Smoking, n (%)			
No	24 (82.8%)	27 (93.1%)	51 (87.9%)
Yes	5 (17.2%)	2 (6.9%)	7 (12.15)
Tendon involved, n (%)			
Supraspinatus	17 (58.6%)	21 (72.4%)	38 (65.5%)
Infraspinatus	2 (6.9%)	1 (3.4%)	3 (5.2%)
Both	10 (34.5%)	7 (24.1%)	17 (29.3%)
Tear, n (%)			
Traumatic	23 (79.3%)	20 (69.0%)	29 (50%)
Degenerative	6 (20.7 %)	9 (31.0%)	29 (50%)
Surgical technique, n (%)			
Open	20 (69.0%)	21 (72.4%)	41 (70.7%)
Arthroscopic	9 (31.0%)	8 (27.6%)	17 (29.3%)
Surgery location, n (%)			
Hospital 1	16 (55.2%)	16 (55.2)	32 (55.2%)
Hospital 2	4 (13.8%)	5 (17.2%)	9 (15.5%)
Hospital 3	9 (31.0%)	8 (27.6%)	17 (29.3%)

Table 7: Demonstrates the rotator cuff status for the groups: by ultrasound at 4, 8 and 12 weeks and MRI at 12-month postoperatively (p=n.s.).

	Synthetic patch	**Control group**	**Total**	**% of the re-ruptured at 12 months**
	n = 29	n = 29	n = 58	
Ultrasound I, (4 w) n (%)				
Total rupture	2 (6.9%)	3 (10.3%)	5 (8.6%)	33%
Ultrasound II, (8 w) n (%)				
Total rupture	5 (18.5%)	6 (22.2%)	11 (20.4%)	73%
Ultrasound III, (12 w) n (%)				
Total rupture	6 (20.7%)	8 (27.6%)	14 (24.1%)	93%
MRI (12 months) n (%)				
Total rupture	7 (24.1%)	8 (27.6%)	15 (25.9%)	
MRI results for the two surgery techniques (12 months) n (%)				
Intact Open surgery	15 (75.0%)	11 (52.5%)	26 (63.4%)	
Partiell ruptur Open surgery	0 (0.0%)	2 (9.5%)	2 (4.9%)	
Rupture Open surgery	5 (25.0%)	8 (38.1%)	13 (31,7%)	
Intact Arthroscopic surgery	7 (77.8%)	8 (100%)	15 (88.2%)	
Partiell ruptur Arthroscopic surgery	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Rupture Arthroscopic surgery	2 (22.2%)	0 (0.0%)	2 (11.8%)	

The MRI result at 12-month follow-up for the 52 out of 58 study patients could be compared with the preoperative MRI, which is demonstrated in the table 8. There were similar MRI findings in the groups without any significant difference. For assessment of re-rupture frequency we used the Sugaya classification (Type I-V, see appendix) [138, 139]. In total, fifteen cases with re-rupture were observed; two type II, three type IV and ten type V).

Table 8: Preoperative and postoperative MRI results for the study groups. For Tangent sign, classifications: Thomazeau, Goutallier and Patte see appendix.

Preoperative MRI, n=52	Synthetic patch n=25	Control n=27
Arthrosis glenohumeral joint		
Yes	1	0
No	24	27
Arthrosis acromioclavicular joint		
Yes	21	22
No	4	5
Tangent sign (Zanetti)		
Positive	12	12
Negative	13	15
Muscle atrophy (Thomazeau)		
Stage 1 (1,00-0,60)	1	4
Stage 2 (0,60-0,40)	16	14
Stage 3 (<0,40)	8	9
Fatty infiltration (Goutallier)		
Stage 0 (normal muscle)	8	7
Stage 1 (some fatty streaks)	14	12
Stage 2 (less than 50%)	3	7
Stage 3 (50%)	0	1
Stage 4 (>50%)	0	0
Tendon retraction (Patte)		
Stage 1	13	14
Stage 2	10	9
Stage 3	2	4

The ultrasound images for two cases both operated with patch shown in figure 19, with intact repair at eight weeks postoperatively, and figure 20 with re-rupture at twelve weeks postoperatively. The patch is completely visible in both images. The radiologist who performed the ultrasounds was however, blinded to patients groups and treatment.

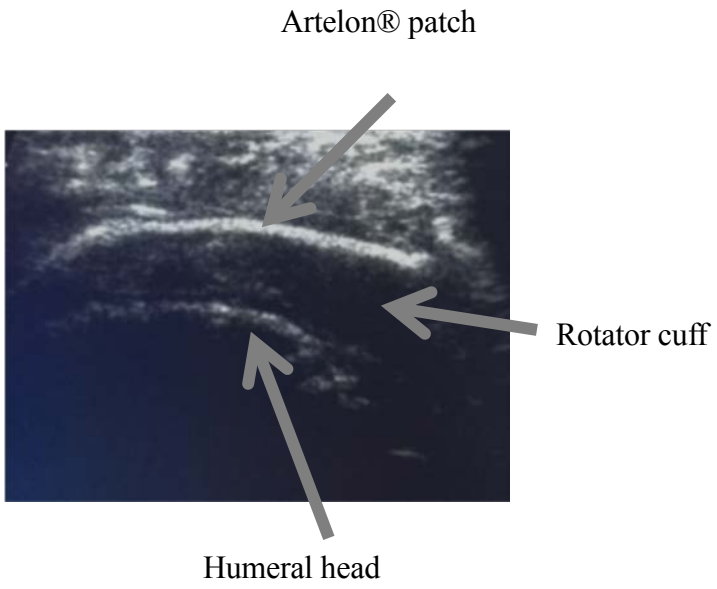

Figure 19: Ultrasound image of a coronal view shows a repaired right shoulder with Artelon® Tissue Reinforcement at 8 weeks postoperatively. The patient is a 62-year-old man. Photo courtesy of Anders Elvin.

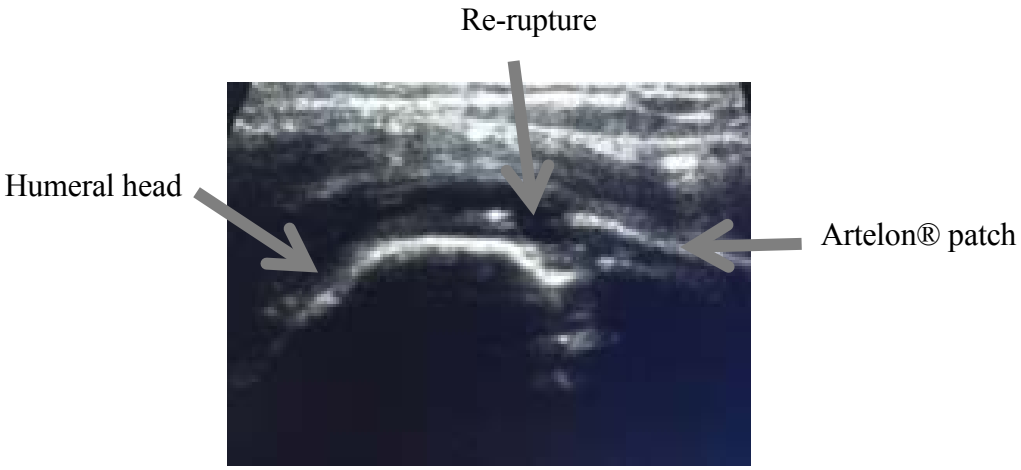

Figure 20: Ultrasound image of a coronal view shows a repaired right shoulder with Artelon® Tissue Reinforcement at 12 weeks postoperatively. The repair is non-intact. The patient is a 61-year-old man. Photo courtesy of Anders Elvin.

The patients in this study were operated with both open and arthroscopic surgery, 42 and 17 respectively. There were similar re-rupture rates between the groups, however re-rupture occurred more frequently in the open surgery group, 31.7% and 11.8% respectively.

In this study the WORC was used as a primary outcome and the result is demonstrated in figure 21, which shows similar outcomes when comparing the pre- and postoperative scoring for the groups. There was no significant difference found in 3-month WORC between the groups. In the whole study cohort the mean WORC score increased from 41% preoperatively to 84% postoperatively (P <0.001). The mean Constant score increased from 39.4 points preoperatively to 75.6 points postoperatively (P <0.001). The mean EQ-VAS increased from 67.5 preoperatively to 83.4 postoperatively (P < 0.001).

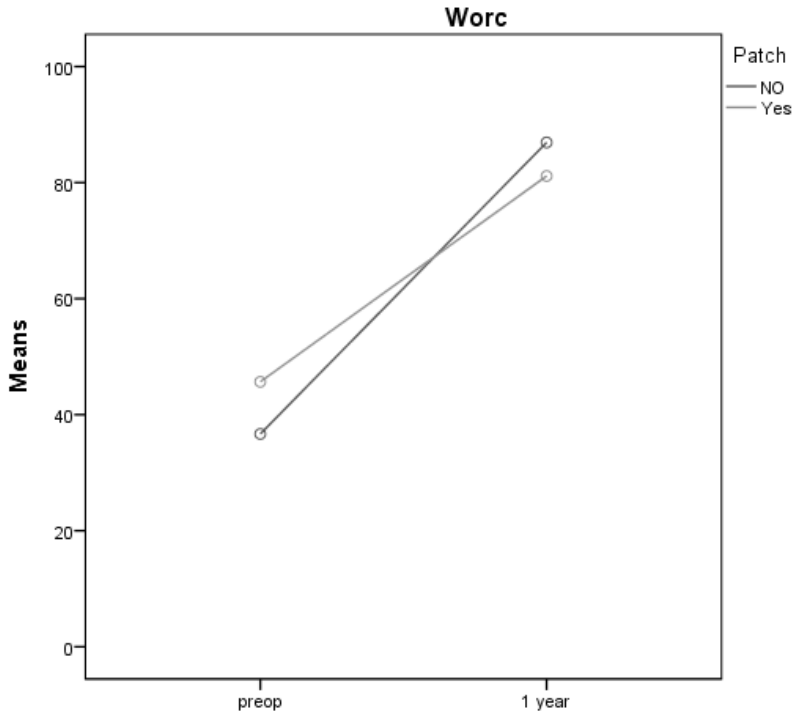

Figure 21: demonstrates the result for WORC score preopertively and at 12-month postopertive for both groups.

In some MRI images the patch could be visualized, however the radiologist who assessed the 12-month follow-up MRI was blinded to the clinical outcomes and patient randomization group. Figure 22 shows a repair with re-rupture and figure 23 shows an intact repair.

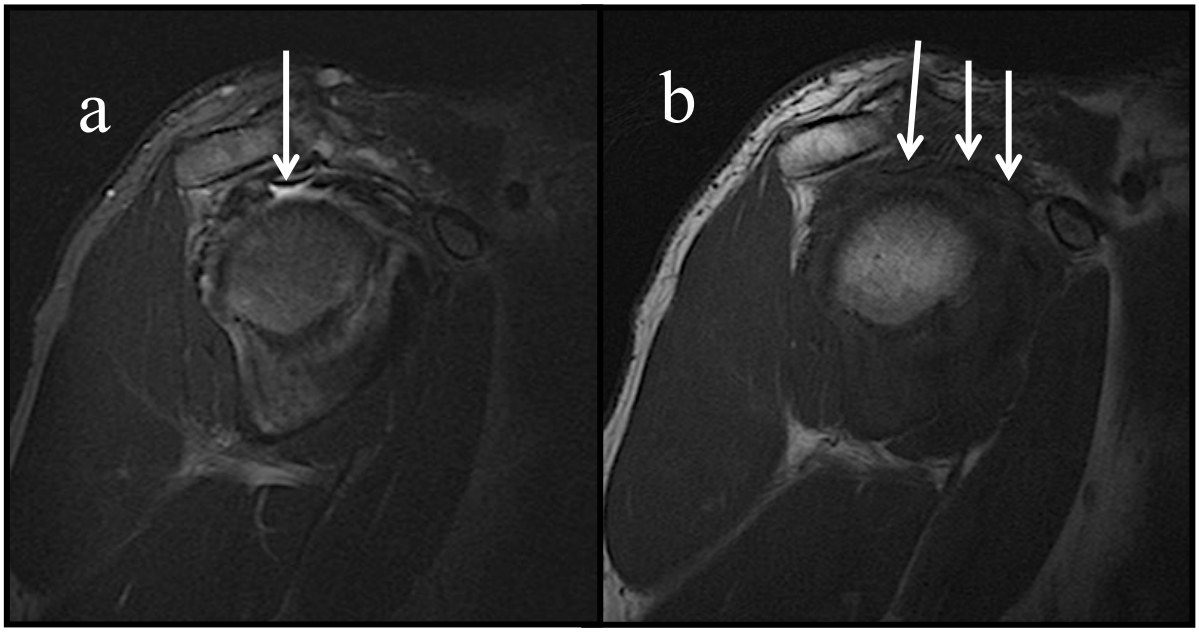

Figure 22: Magnetic resonance imaging of the right shoulder at 12-month follow-up. The cuff is repaired with Artelon® Tissue Reinforcement in a 58-year-old man.
a) Sagittal oblique T2-weighted fatsat image b) Sagittal oblique T1-weighted image. Both a and b demonstrate re-rupture cuff and visible patch. Photo courtesy of Anders von Heijne.

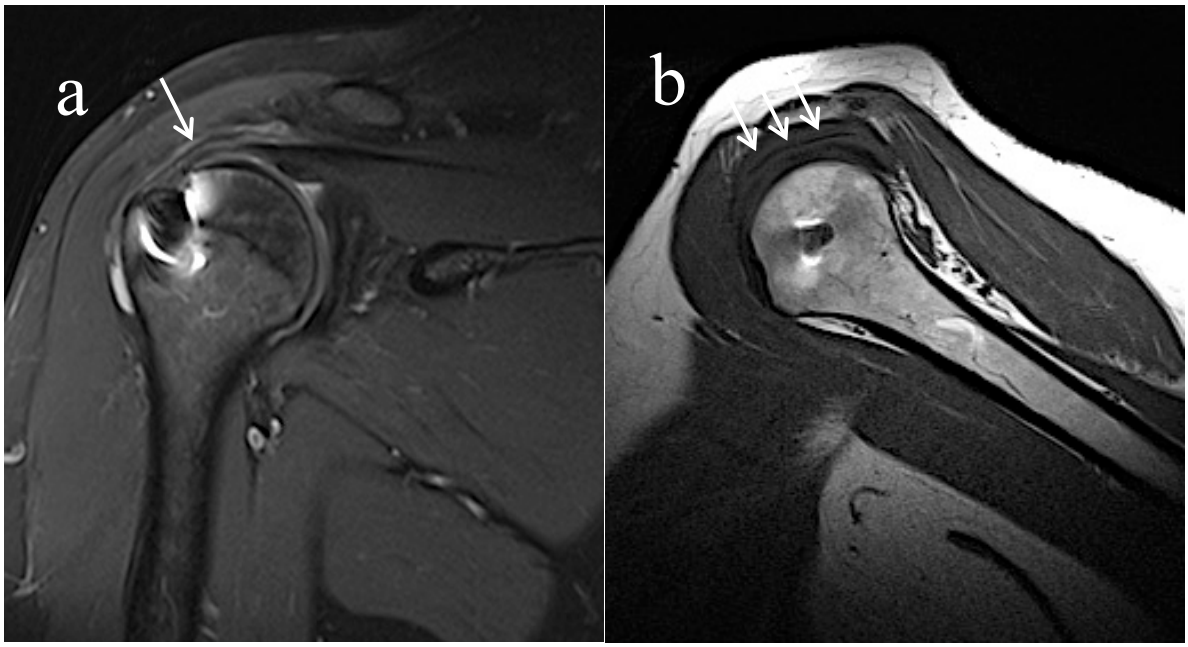

Figure 23: demonstrates magnetic resonance imaging of the left shoulder at 12-month follow-up. The cuff is repaired with Artelon® Tissue Reinforcement in a 53-year-old woman.
a) Coronal oblique PD-weighted fatsat image b) Sagittal oblique T1-weighted image. Both figure a and b demonstrate intact repair with visible patch. Photo courtesy of Anders von Heijne.

8 GENERAL DISCUSSION

Surgical treatment of the RC has been in use since Codman introduced it in 1911[22] yet, indication, timing, and eligibility of candidates for RC surgery is still a matter of debate among orthopaedic and shoulder surgeons. This is likely due to the fact that treatment recommendations in symptomatic full-thickness rotator cuff tears are based on expert opinion with weak level of evidence [115]. In this thesis the indications for surgical treatment of symptomatic degenerative and traumatic rotator cuff tears including the factors impacting on the results have been studied. In study I, we investigated appropriate timing for surgery in TRCT in order to elucidate better knowledge in this field. In study II the Swedish version of WORC, a diagnosis specific QoL score, has been validated for evaluation of treatment in patients with subacromial pain including rotator cuff tear. In study III, predictors for rotator cuff surgery results were investigated through comparison of pre- and postoperative MRI. In study IV we compared rotator cuff repair with or without synthetic patch augmentation in a RCT settings.

8.1 SURGICAL VS NON-SURGICAL TREATMENT

The indication for surgical rotator cuff repair is a painful shoulder refractory to nonsurgical management. Symptomatic RCT can be successfully treated with both non-operative and operative treatment however, for patients with chronic symptoms lasting more than 6 months the results with non-operative methods are unsatisfactory. Pain free status may be achieved by simple debridement and decompression [124] but improvement in function can reasonably be expected only if the overall kinematics about the joint can be restored [104]. This goal can preferably be reached with complete repair of the RC tendons, although a partial repair has also been reported to restore the shoulder function and improvement of Constant scores, as well as sufficient patient satisfaction and autonomy [45]. The best result in RC repair with lowest failure rate has been reported in one tendon tears in patients younger than their sixties. A recurrent rate higher than 50% can be expected when more than one tendon is torn, especially in elderly.

Intact repair resulted in good function and patient satisfaction as compared to shoulders with non-intact repair [52]. RC tears advance in size and retraction and develop muscle atrophy and fatty degeneration with time, which deteriorates the outcomes of future surgery. It has been shown that the most common reason for rotator cuff muscle atrophy is chronic rotator cuff tears [6, 46, 91]. Atrophy of RC muscles and fatty degeneration has been considered an irreversible phenomenon [38, 44, 47, 77] but there are some studies available that suggest that surgical cuff repair may halt the atrophy of RC muscles [145] and even promote a postoperative improvement in the case of successful cuff repair [19, 113, 152]. Furthermore, it is well known that the muscle atrophy and fatty degeneration are some of the most important prognostic factors for anatomic healing and for the functional result following a surgical cuff repair [44, 47, 88, 89]. Based on the results of these observations, surgical repair should be considered in agreement with patient when technically possible. There is not

enough evidence in the literature to motivate waiting and postponement of the surgery until a later date. In a retrospective study of 218 patients in 2007 Lähteenmäki et al. stated that repair of full-thickness rotator cuff tears is recommended regardless of tear size and age if patients have any symptoms, especially pain [73].

McKee et al. stated that surgery of chronic RC disease reliably and significantly improves general health status [86]. Arthroscopic rotator cuff repair has also been shown to be a successful procedure also in patients aged ≥70 years. However, the gender and age of the patient are important factors to consider when planning management [123]. Kweon et al. compared surgical to non-surgical management of RC tears in a total of 196 patients with known full-thickness RC tears and reported (2015) that patient demographic at the time of initial presentation for a symptomatic RCT were more predictive of treatment allocation to a surgical or non-operative approach than the patient-derived outcome scores for activity level and shoulder disability. However, they emphasized that further studies were needed to help define appropriate indications for treatment allocation in patients with RCT [72].

The tear size increases with time and massive rotator cuff tears present several challenges for orthopaedic surgeons. Many rotator cuff tears can be repaired while some chronic rotator cuff tears require advanced reconstructive techniques. Repair, if possible, is the optimal treatment for rotator cuff tears [14]. In massive irreparable cuff tears muscle transfers are an option for patients younger than 60 years who do not have pseudoparalysis. Arthroplasty is an option for older patients who have concomitant arthritis and for patients who have pseudoparalysis. Biologic augmentation in the setting of RCT continues to evolve, and the application of biologic products should be guided by sound evidence and cost-benefit considerations, as stated by Burkhart et al. [14].

In 2015 Kukunen et al. investigated the optimal treatment of non traumatic RCT in 160 patients in a prospective randomized controlled trial with two years of clinical and MRI imaging follow-up. They compared cuff repair with physiotherapy-only and acromioplasty plus physiotherapy and found out no difference between the groups therefore they could There was no significant difference in clinical outcome between the three interventions at the two-year follow-up. The potential progression of the rotator cuff tear, especially in the non-repaired treatment groups, warrants further follow-up. Conservative treatment is a reasonable option for the primary initial treatment for isolated, symptomatic, non-traumatic, supraspinatus tears in older patients [71].

On the other hand, Park et al showed that in small to medium-sized rotator cuff tears, grade II fatty degeneration of the infraspinatus muscle according to the Goutallier classification could be a reference point for successful healing, and anatomic outcomes might be better if repair is performed before the patient is 69 years old and the tear size exceeds 2 cm [112].

8.2 SURGICAL METHODS

Several studies have compared arthroscopic with open and mini-open techniques for tears of all sizes and have shown similar results [3, 13, 58, 64, 151, 154]. In a recent study no

evidence was found on the superiority of arthroscopy versus open repair of rotator cuff tear concerning the postoperative pain level therefore the choice of the surgical technique should not be based on this argument [117]. In a review article from 2016, Huang et al. stated that all-arthroscopic and mini-open repair surgical techniques for the management of RC repair are associated with similar outcomes and can be used interchangeably based on the patient and rotator tear characteristics [54]. The patients in study IV were operated with both of the methods; open technique was used in 32 patients (two surgeons) and arthroscopic technique (two surgeons) in 17 patients. The re-rupture rate was 26% (15 cases), seven cases in the patch group and eight cases in the control group with no significant difference (p=0.319) despite the surgery technique. However the re-rupture rate was lower in arthroscopic operated patients, 11.8% compare to 31.7% in the open group. Duquin et al. concluded in a systematic literature review, published in 2010, that the surgical approach had no significant effect on re-rupture rate [30]. In our study (study IV) the open surgery group consisted of 31.7% two-tendon tear while the arthroscopy group of 23.5%, yet this difference was not significant. The number of patients was too small to assess differences between the surgical methods.

8.3 THE INFLUENCE OF TIMING IN TRAUMATIC CUFF SURGERY

Traumatic rotator cuff tear (TRCT), defined as an onset of symptoms following an acute shoulder trauma, is usually treated by primary surgical repair, as recommended [2, 74]. The timing for surgery in TRCT has been subject to disagreement among orthopaedic surgeons of the belief that late surgery would lead to worse surgical outcome compared to early surgery. The national orthopaedic guidelines in Sweden recommend repair within three weeks of injury in order to achieve the best outcome [140]. This recommendation is based on one study from the 1980s [2]. Since then, in contrast a few studies have shown good results in patients who had undergone surgery a few months after the injury. Two studies published in 2011 by Björnsson et al. (42 patients) and Petersen et al. (36 patients) reported similar and good results for surgical repair both early and late, within the time span of up to three or four months after injury [8, 116]. At the same time Dante et al. in a study including 35 patients showed that early repair, within three weeks, provided better results in terms of shoulder function in comparison to delayed repair [51]. However, in 2013, Muskovozov et al. conducted the first systematic review in order to assess the time of surgery in acute RCT and they divided the studies into two groups, surgery < three months, and surgery > three months after injury. They found a trend suggesting that earlier time to surgery may be linked to better Constant scores and range of movement although the conclusion was that additional well-designed comparative studies were needed in this field [97].

In our study, with the largest cohort reported to date on this subject, there were 73 patients (75 shoulders) included. These patients were divided in two groups, early (surgery within three months after injury) and late (surgery > three months after injury) with a postoperative follow-up time at least one year. The result of this study showed similar results in all the outcomes measured between the groups.

Shoulder trauma frequently causes TRCT, and the diagnosis may often be missed on the first clinical examination. An incidence of more than 50% of RCT has been found in patients over

50 years of age after shoulder trauma. However, in the absence of a fracture around the shoulder, patients are often discharged from the emergency department without a correct diagnosis [137], therefore diagnosis of an acute RCT after trauma is possibly missed and the treatment may be delayed. Thus, it is of the utmost importance that this group of patients does not miss their chance for surgery if indication otherwise exists. Due to the direct trauma to the shoulder, these tears are usually large or massive (involvement of two or even three tendons) and reattachment of the tendons when surgery is delayed is more difficult [48, 99].

8.4 MAGNETIC RESONANCE IMAGING AND ULTRASOUND IN ROTATOR CUFF DIAGNOSTIC

All of the 58 patients in study IV underwent a postoperative MRI of the repaired shoulder at 12-months follow-up. Of these 58 patients, 52 had also preoperative MRI investigations available, which we could use for comparison. All the MRI images were assessed by a senior musculoskeletal radiologist, blinded to he patient surgery group and clinical outcomes, with regard to cuff integrity, muscle atrophy and fatty degeneration for both intervention groups.

The Thomazeau 3-stage grading classification was used for assessment of muscle atrophy and fatty degeneration based on Goutallier 5-stage grading classification (see appendix).

Ultrasound imaging has become a popular and well-established modality for evaluating rotator cuff pathology because of its low cost and noninvasive nature. It has proven to be reliable in identifying the presence of a tear, even during the postoperative period [37, 119]. In study IV, all the 58 patients underwent follow-up with serial ultrasound 4, 8 and 12 weeks after the RC repair surgery. With this investigation technique we aimed to carefully assesse the patients post-surgery progress in order to not overlook early complications and at the same time observe the similarity or differences between the patch and control group. The timing for these assessments was carefully chosen in consultation with the senior radiologist involved in the study. We choose to start with ultrasound investigations 4 weeks after the surgery, when the postoperative pain and reactions had settled and slightly movement of the arm in the operated shoulder deemed to be risk-free. Based on the fact that the majority of re-ruptures are thought to occur within three months after repair, we proceeded investigation at 8 weeks and lastly at 12 weeks [68, 93]. The findings of our study lend support to this statement, as 93% of the re-ruptures were observed within three months. These findings were later confirmed at the 12-months MRI follow-up. Only one more re-rupture was observed at 12-month for the whole group. The senior radiologist performing the serial ultrasound was blinded to patient surgery group and clinical outcome.

8.5 PARTIENT-REPORTED OUTCOME MEASURES

In the wake of the introduction of hip joint replacement in 1960s [17] and arthroscopic surgery in 1980s, patient-reported outcome measures (PROM) is the most revolutionary improvements that have evolved in orthopaedics since the 1990s after. As the patient's own perception of changes in health status is the most important indicator of the success of

treatment it has been suggested that this measurement tool be used as the primary outcome in the clinical evaluation

The development of a suitable PROM, by orthopaedic surgeons who wish to measure the outcomes of their treatments from the patient perspective, has been in focus during the past decade. Lo et al. stated that the patient's own perception of changes in his or her health status is the most important indication of the success of treatment [79]. As patient involvement in outcome assessment is becoming more widely established, it is becoming increasingly important to achieve some standardization in the use of these instruments.

A common problem with questionnaires is that some patients provide incomplete responses (missing data). It has been proposed that if, after repeated attempts to obtain complete data from an individual, only one or two questions have been left unanswered, it is reasonable to enter the mean value representing all of their other responses, to the gaps. Jenkinson et al. reported an alternative computerized method of imputing values, which could be applied to many questionnaires [59]. If more than two questions were unanswered they believed that an overall score should not be calculated. If patients indicated two answers for one question it was recommended that the convention of using the worst (most severe) response to be adopted.

Changes in scores on health status questionnaires are difficult to interpret [146]. For the WORC which has been used in this thesis, the Minimal Clinically Important Changes (MCIC) has been calculated to be 275 points, or 12.8 % if presented in the mode of WORC% [31]. This was in line with the developers of the WORC index own description of Minimally Important Difference (MID) 11.7 % [66].

8.6 SYNTHETIC AUGMENTATION IN ROTATOR CUFF SURGERY

In the past decade a notable interest has emerged to develop new treatment strategies that provide effective mechanical reinforcement of RC repair and also stimulate intrinsic healing potential. Longo et al. have thoroughly studied the available data in regard to synthetic augmentation in massive rotator cuff and concluded that the available data are lacking to allow definitive conclusion on the use of these scaffolds [80]. Future investigations are certainly required to evaluate the role of synthetic scaffolds in the clinical practice. However, there are some advantages with the synthetic patches in comparison to biological augmentations such as no risk for blood-transmitted disease, easy to handle and transport. Improvements are needed to address the often-poor tissue quality of the degenerated rotator cuff tendons. Current biological solutions provide only short-term reinforcement and have been associated with pseudo-infectious reactions. On the other hand the polyurethane scaffolds such as polycarbonate polyurethane patch for tissue extension or augmentation in RC repair have demonstrated no inflammatory response and excellent tissue integration in a rat rotator cuff repair [24].

Another aspect of augmentations in rotator cuff surgery is their mechanical properties. Chaudhury et al. [18] conducted a study in 2012 to determine the tensile and shear mechanical properties of the commercially available RC repair patches. They tested Restore,

Graftjacket, Zimmer Collagen Repair and SportMesh (Artelon® Tissue Reinforcement) and found out that all these displayed significant variation in their mechanical properties and had at least some reduced parameters compared with human RC tendons. They concluded that a better understanding of the mechanical suitability of repair grafts for supporting human RC is needed if repair patches are to provide a solution for the clinical problem of failure in RC repair [18].

Before we conducted the study IV, a randomized controlled trial to compare result of RC repair with and without a synthetic patch, we carried out a pilot study and augmented a few patients with RC repair with Artelon® (Zhaeentan et al 2011). One of the patients, an 81-year-old man has been followed-up for five years post-surgery and the MRI images are demonstrated in figure 24.

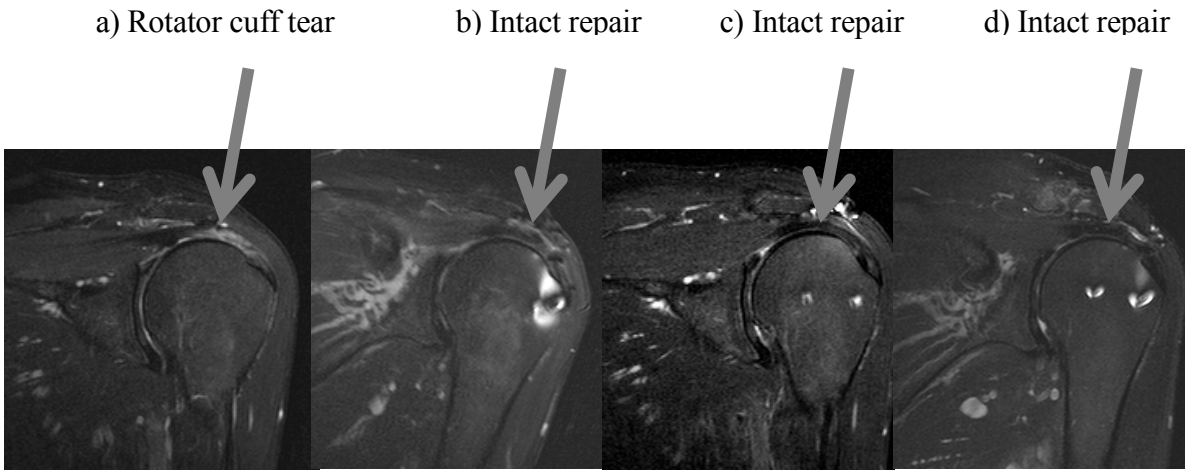

Figure 24: MRI images of a left shoulder (COR OBL T2w with fat saturated; 1,5 T) of a full-thickness Supraspinatus tear in an 81-year-old man who underwent repair with an Artelon® patch in 2008. At the time for MRI investigation five years later, 2013, the patient presented with a pain-free shoulder and full range of motion. He reported that he did not feel any limitation in his daily life. a) Preoperatively, b) 5 months, c) 15 months and, d) 5 years postoperatively. Photo courtesy of Anders von Heijne.

The Artelon® has been used also as a soft tissue augmentation in the dental field and stable results have been achieved for up to six months [69]. Furthermore, Artelon CMC Spacer showed initially favorable clinical outcomes as an interposition material in arthritic CMC joint, however due to an unacceptably high complication rate it is no longer used in this field [122].

The available data from a few studies, as well as our own study (IV) with serial ultrasound investigations have shown that the greatest risk for re-rupture after RC repair is within the first three months after surgery [68, 93] therefore a scaffold need not necessarily be permanent or degrades over several years as for Artelon®. The main reason for most RC tears are weakened and degenerative-changed tendons as well as hypovascularity of the RC [85], and consequently, a scaffold should enhance the healing properties of the RC and reinforce the repair at the same time.

9 LIMITATIONS

There are some limitations in this thesis. In the studies I and III, the main limitation is basically due to the nature of the study i.e. being a retrospective study, which consequently includes selection bias. In study I, 124 patients were eligible for the purpose of the study of which 12 were not available and finally 112 were invited to participate. Of these, 75 (67%) patients agreed to attend. This raises the question why those other 37 did not respond. We send a second letter to these individuals and asked them to explain their reasons and also complete the WORC questionnaire. Fourteen of the 37 (38%) returned completed WORC scores and they explained their reasons for declined attendance. The main reasons were either lack of time or an unwillingness to fill out the questionnaires, nevertheless all fourteen returned the completed WORC questionnaire and their scores were comparable to the actual study subjects as well as their mean age. Study I also deselected those individuals who were not candidates for surgery and there is no follow-up of patients with non-surgical treatment accessible for comparison. However, the strengths of this study are the number of patients included and the long follow-up time. In addition, the main author was not involved in the surgery of the study subjects and acted as an independent investigator of the results.

The long time interval between the test-retest in study II might be subject for study limitation. A range from 36 to 367 days between the tests perhaps can be considered to be too long to ensure symptom stability, nevertheless the optimal interval for a test-retest has not been settle [81]. Due to the excellent reliability the analysis showed it could be concluded that the patient had come to a stable phase a minimum of one year from surgery.

Study III has a few limitations in addition to the selection bias explained above. In this study the same senior radiologist assessed all the MRI images both preoperatively and the MRI at follow-up, however it was at least one year between these assessments and the radiologist was completely blinded to the clinical outcome and in study I also to the patient surgery group. The aim of this study was not to address the validity or reliability of the MRI in rotator diagnostic as this has been already demonstrated in the 1990s and later on in several studies [57, 155, 157]. Furthermore the methodology used in MRI evaluation could be a source of bias. Goutallier classification[46] (see appendix) is currently the gold standard in evaluation of RC muscle fatty degeneration. There are mixed reports about inter-observer reliability in Goutallier classification, some authors have been reported a low inter-observer reliability [78, 108, 135] and some both high inter observer and intra-observer [128]. Other authors have suggested different kinds of MRI resolution such as chemical shift MRI to obtain a higher accuracy and reliability[76]. However, the strength of study III is the long follow-up time and the comparably large size of the cohort

Study IV is a well-conducted patient-blinded randomized controlled study with substantial number of study subjects included with 12 months clinical and radiological follow-up. However, the strength of this study is limited due to the fact that the calculated power was not met and a study with a larger number of participants might have shown differences between the two intervention groups. Also, in this study the one single senior radiologist assessed the preoperative MRI and MRI at the 12-month follow-up. The radiologist however, was blinded to the surgery intervention group and the clinical outcome. Another limitation in this study is that in 17 of 58 cases surgeons performed the ultrasounds themselves due to the hospital's

remote location with respect to our radiology department, however two different surgeons were contributing and when possible they did not carriy out the ultrasound investigation on their own patients. Their ultrasound findings were in agreement with the results in the 12-month MRI follow-up. The follow-up of study patients in study IV was carried out, in some cases by the surgeons themselves and in other cases by an independent physiotherapist, which might create the risk that those patients, reported more favorably to the surgeons rather that to the physiotherapist.

During the study (IV) period the augmentation patch (Artelon® Tissue Reinforcement) which, was used was withdrawn from the market, and if it will not be available again, then the clinical usefulness of this study will not meet its full potential to the patients, which could be considered as a limitation of the study.

10 CONCLUSIONS

Study I

The surgical repair of symptomatic TRCTs repairable later than 3 months after injury yields a good functional outcome with a high level of subjective patient satisfaction similar to the results obtained when surgery is performed within 3 months after injury. Based on the findings in this study, surgical repair could be encouraged whenever indicated irrespective of the timing from injury.

Study II

The Swedish-version of the WORC instrument can be considered reliable, valid, and responsive for use as a health measurement instrument on patients treated by surgery for rotator cuff syndrome and subacromial pain. The psychometric properties of the Swedish version of the WORC were in line with the original evaluation, as well as evaluations of various translations of the WORC

Study III

Preoperative tendon retraction of more than 40 mm is associated with a fivefold re-rupture risk after rotator cuff repair. The presence of muscle atrophy and fatty degeneration (e.g. Goutallier stage 3 and 4) on preoperative MRI were also significantly negative predictive factors for re-rupture. Furthermore, it is shown that surgically treatment prevents progression of muscle atrophy and fatty degeneration in up to 65% of all the repaired shoulders. This result may encourage considering surgery for symptomatic RCT when technically possible.

Study IV

The use of a synthetic patch (Artelon® Tissue Reinforcement) in rotator cuff surgery can not be recommended routinely as the postoperative results in this study have not been superior to a repair without patch. Nevertheless, the use of Artelon® Tissue Reinforcement is safe and has high patient satisfaction without any additional post-operative morbidity.

11 FUTURE RESEARCH APPROACH

- An already on-going study with a larger patient material will be evaluating the timing for re-rupture after rotator cuff surgery with serial ultrasonography at 4, 8 and 12 weeks postoperatively. The control group from the study IV will be included in this study.

- All the patients included in study IV are going through a two years follow-up with WORC- score and they will be contacted for a five-years follow-up with MRI and clinical outcome assessment starting in February 2017 and continuing until April 2020.

- As the current knowledge indicates that the majority of re-ruptures occur early, within 3 months postoperatively, after RC repair the attention for future research should be directed to improving the early healing of the repair and optimization of the postoperative regime.

- The future researchers are encouraged to conduct randomized studies on augmentation with synthetic patches to compare different scafolds with each other and to control groups. Orthopaedic surgeons are challenged to assess a large amount of otherwise healthy elderly patients with high demands on functionality and quality of life. There is still an unacceptably high rate of failure in rotator cuff surgery and it is therefore essential to identify aiding factors in order to improve the success of rotator cuff repair strategies.

- Rotator cuff disease has been a significant focus of research activity in recent years, as orthopaedic surgeons face the challenge of poor tendon healing and the consequences of irreversible changes related to rotator cuff arthropathy. Future treatment modalities involving tissue engineering hold further promises to improve outcomes as well as studies on genetic influences and gene expressions profiles in individuals with rotator cuff disease which might lead to tailored future treatment options in the future.

12 POPULÄRVETENSKAPLIG SAMMANSTÄLLNING

Axelleden är en av de största och mest komplicerade lederna i kroppen. Axelleden har en grund ledpanna och därför hålls ledkulan på plats av kringliggande senor, ledband och ledkapsel. Friska och välfungerande muskler och senor är av yttersta vikt för axelns normala funktion. En grupp av fyra muskler och deras senor bildar en senmanschett som kallas rotatorcuff. Rotatorcuffen möjliggör det omfattande och unika rörelseomfånget i olika plan som axelleden klarar. Smärtor i axelleden kan orsakas av förändringar eller bristningar i rotatorcuffen. Skador i en eller flera av axelledens senor kan orsaka stort lidande och nedsatt funktion hos de drabbade individerna. Förutom svårigheter att genomföra vardagliga aktiviteter lider dessa individer även av rörelsesmärta, vilovärk och nattliga besvär som stör sömnen. I de flesta fall är det normala åldrandet (degeneration) grund till bristningar i rotatorcuffens senor, vilka även kan uppstå i kombination med mindre eller större trauma.

Sjukdomar i rotatorcuffen är överrepresenterade i vissa yrkeskategorier såsom elektriker, målare och frisörer, vilka alla arbetar mycket med armarna över axelplanet och riskerar därför oftare att få besvär med sina senor. Enligt försäkringskassans statistik för 2009 uppgick kostnaderna för rotatorcuff och de skuldersmärta-relaterade diagnos-koderna upp emot 900 miljoner kronor. Kostnaderna för arbetsgivaren är inte medräknade i detta. Det faktiska mänskliga lidande är dessutom svårt att mäta. En förbättring och effektivisering av behandlingen av dessa åkommor har med stor sannolikhet dessutom samhällsekonomiska fördelar.

Det är välkänt att bristningar i rotatorcuffen förekommer i individer över femtio år men när dessa ger symptom drabbas individen av påtaglig funktionsnedsättning och därmed reducerad livskvalitet. Mellan 50-60 års ålder är det 20-30 % som har bristningar i sin rotatorcuff men över 80 års ålder är siffran upp till 50 %. Trots bristning har inte alla faktiska besvär i sin axel men det är bevisat att över hälften av dessa individer utvecklar symtom inom tre år.

Skador i rotatorcuffen kan repareras kirurgiskt, ofta med gott resultat, men fortfarande trots utvecklingar av modern kirurgisk metodik förekommer en hög frekvens av läkningskomplikationer (20-70 % i olika material) där den reparerade senan har en kvarstående, eller återfall av, skada (re-ruptur). Det beror i de flesta fall på dålig kvalitet på senorna vid reparationen. Första gången det publicerades en text om rotatorcuff-rupturens existens var år 1788 men trots att det har gått 228 år sedan dess finns det många obesvarade frågor kring handläggning och behandling av bristningar i rotatorcuffen. I detta avhandlingsarbete diskuteras några av dessa oklarheter och det tillförs ny kunskap inom forskningsområdet. Intresset för axelbesvär som orsakas av sjukdomar i rotatorcuffen har ökat explosionsartat och det pågår intensiv forskning kring problemet världen över. En anledning till detta kan vara att befolkningen blir allt äldre, och dessa äldre individer har allt högre krav på funktion och välbefinnande.

Detta avhandlingsarbete består av fyra delarbeten. Nedan berörs syftet och resultatet för respektive delarbete:

Studie I: Syftet med denna studie var att undersöka betydelsen av tiden från skada till operation för traumatiska rotatorcuff-rupturer i axlar där symtomen har satts igång efter en känd skada såsom ett fall, ett tungt lyft eller liknande. Den allmänna uppfattningen bland ortopeder är att operation inom några få veckor leder till bättre utfall. I denna studie ingick 73 patienter som hade opererats för en akut rotatorcuff-ruptur på vår klinik. Patienterna undersöktes med magnetkamera (MR) och klinisk undersökning samt fyllde i flertalet frågeformulär om sin axel funktion.

Patienterna delades in i två grupper, de som hade opererats inom tre månader och de som hade opererats senare än tre månader efter skadan. Dataanalysen visade att båda grupperna hade likvärdiga resultat i samtliga parametrar som utvärderades. Slutsatsen är att om kirurgi är möjligt så är tiden efter skada inte avgörande för ett bra resultat. Vi rekommenderar att tiden från skada inte ska påverka beslutet när man överväger operative åtgärd av en rotatorcuffskada.

Storleken på denna studie material är större än tidigare publicerade studier.

Studie II: Användning av sjukdomsspecifika patientevaluerande frågeformulär har varit ett av de mest revolutionerande framstegen inom ortopedin sedan nittiotalet. I detta arbete har vi validerat ett axelspecifikt frågeformulär Western Ontario Rotator Cuff index (WORC) för utvärdering av åkommor orsakade av trängsel och trasiga senor i axeln, på svenska språket. Frågeformuläret är initialt framtaget på engelska men har sedan 2003 översatts och validerats på mer än nio olika språk. Fördelen med WORC är att patienten fyller i enkäten helt självständigt, samt att den lämpar sig även för utvärderingar av operationsresultat för jämförelse mellan olika kliniker och sjukhus. I denna studie ingick två grupper av patienter. I ena gruppen ingick det 65 patienter som besvarade WORC och tre ytterligare frågeformulär före, och sex månader efter, sin axeloperation. Resultatet från dessa frågeformulär jämfördes med varandra och analyser visade att WORC var tillförlitlig för utvärdering av denna patientgrupp. För reliabilitet av detta instrument användes 49 patienter som ingick i delarbete I och som besvarade WORC i en test-retest modell. Denna studie visade att WORC i svensk översättning är pålitligt och användbart för utvärdering av behandlingsresultat i den aktuella patientgruppen.

Studie III: Syftet med denna studie var att se huruvida magnetkameraundersökning (MR) av rotatorcuffens muskulatur och skadade senor före en operation skulle kunna förutse resultatet efter operation. I denna studie använde vi oss av patientmaterialet i delarbete I där en MR undersökningar efter operationer redan fanns. Av dessa patienter hade 62 patienter hade även en MR undersökning innan operation som kunde jämföras med postoperativa MR undersökningar. Vi utvärderade förekomst av fettdegeneration, muskel-förtvining, sen-retraktion och betydelsen av dessa för ett dåligt läkningsresultat (re-ruptur). Dessa faktorer jämfördes även med patienternas funktion och nöjdhet. Vi kunde visa att en brusten sena som var tillbakadragen med över 40 mm före operation var den överlägset avgörande faktorn för ett misslyckat operationsresultat och ökade risken för re-ruptur femfaldigt. Även förekomst av svårare grad av fettomvandling och muskelförtvining försämrade utsikten för lyckad operation. Vi kunde dessutom visa att en lyckad operation inte bara kunde stoppa progressen

av fettomvandling och muskelförtvining hos mer än 50 % av patienterna men även ge en förbättring i vissa fall. Resultatet av denna studie kan vara till stöd för en bedömning inför operation i denna patientgrupp.

Studie IV: Genom åren har man försökt förbättra prognosen för patienterna som opereras för rotatorcuff-skador genom att förstärka senan med olika tillförda material. Man har försökt med t.ex. tarm-vävnad från gris och mänsklig hud. Intresset har dock riktats mot syntetiska (konstgjorda) material, vilket har flera fördelar. Dessa är mycket lättare att hantera/transportera samt att det inte finns risk för överförbara sjukdomar eller avstötning. Det har visats sig vara mindre risk för postoperativa infektioner med syntetiska material. Olika typer av syntetiskt material för förstärkning av rotatorcuffen har använts världen över de senaste femton åren och de rapporterade resultaten är lovande men det finns inte kontrollerade randomiserade studier i ämnet. Detta är en prospektiv randomiserad studie, vilket anses vara det främsta forskningsformatet. Denna studie var dessutom blindad för patienterna, d.v.s. de fick inte veta vilken operationsmetod som användes, vilket anses höja värdet på studien ytterligare.

Syftet med denna studie var att undersöka huruvida en svensk-tillverkad syntetisk förstärkning i form av en textil-liknande lapp (patch) skulle kunna förbättra resultatet efter rotatorcuff-kirurgi. I denna studie ingick 58 patienter med brustna axelsenor som lottades till antingen traditionell reparation utan förstärkning, eller till samma operation med en förstärkning av senan. Hälften av patienter blev opererad med patch och hälften utan. Patienterna har noggrant följts, före och efter operation, med frågeformulär samt upprepade ultraljudsundersökningar vid 4, 8 och 12 veckor efter operation. Slutlig uppföljning med MR och klinisk undersökning ägde rum 12 månader efter op. Patienterna informerades vid 12 månader huruvida de hade fått förstärkning eller inte, detta var överenskommet med patienter vid tiden för inkludering i studien. Denna studie har inte kunnat visa att kirurgi med syntetisk förstärkning är överlägset den traditionella metoden. De två grupperna visade liknande resultat i samtliga analyserade parametrar. Inga allvarliga postoperativa komplikationer inträffade i någon grupp och re-rupturfrekvensen var densamma i bägge grupper på 24 %, vilket är ett förväntat resultat efter rotatorcuff-kirurgi.

Såvitt vi vet är detta den första prospektiva randomiserande studien avseende denna frågeställning.

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"I shall either find a way or make one”

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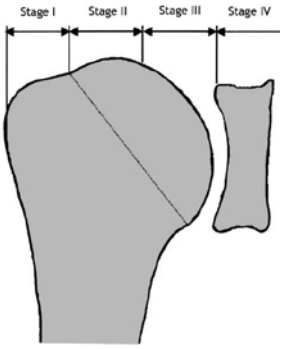
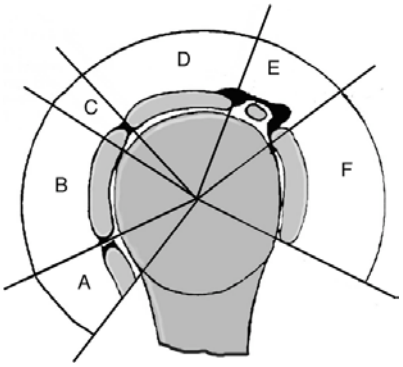
15 APPENDIX



a) Coronal size and extent of supraspinatus tear



b) Sagittal size and extent of supraspinatus tear

Boileau classification [10]: Tears stage II or III in sector B-C or D, alone or in combinations, were included in study IV.

Goutallier classification [46]: Fatty degeneration of cuff muscles

- Stage 0 - Normal muscle
- Stage 1 - Some fatty streaks
- Stage 2 - Less than 50% fatty muscle atrophy
- Stage 3 - 50% fatty muscle atrophy
- Stage 4 - Greater than 50% fatty muscle atrophy

Patte classification [114]: Classification of tendon retraction, MRI image in the coronal plane.

- Stage 1: proximal stump close to bony insertion;
- Stage 2: proximal stump at level of humeral head;
- Stage 3: proximal stump at level of glenoid.

Sugaya classification [138]: Postoperative cuff integrity classification

- Type I = sufficient thickness compared with normal cuff with homogenously low intensity on each image
- Type II = sufficient thickness compared with normal cuff associated with partial high intensity area
- Type III = insufficient thickness with less than half the thickness when compared with normal cuff, but without discontinuity, suggesting a partial-thickness delaminated tear
- Type IV = presence of a minor discontinuity in only 1 or 2 slices on both oblique coronal and sagittal images, suggesting a small full-thickness tear
- Type V: presence of a major discontinuity observed in more than 2 slices on both oblique coronal and sagittal images, suggesting a medium or large full-thickness tear.

Thomazeau classification [145]: Supraspinatus muscle atrophy on MRI

Occupation ratio R = S1 / S2

S1= surface of supraspinatus muscle

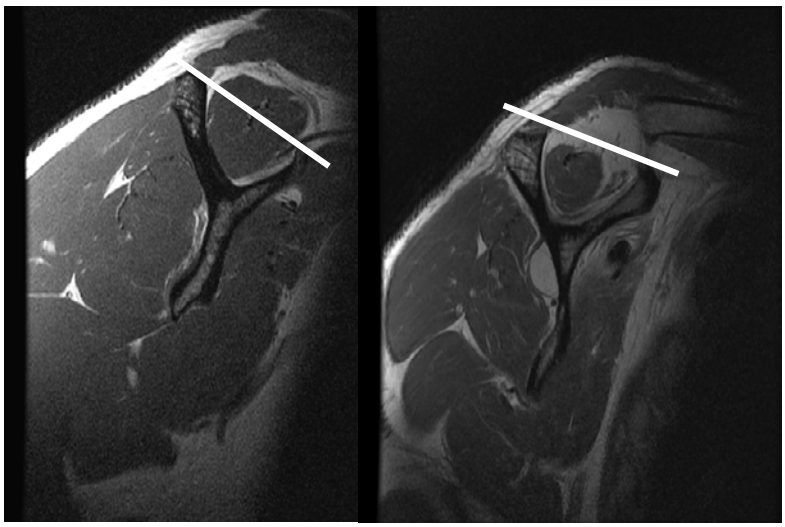
S2= surface of entire supraspinatus fossa

Measurement on the scapular cut at level of medial border of spine of scapula.

- Stage 1: Normal/ slight atrophy Occupation ratio (1.00-0.60)
- Stage 2: Moderate atrophy Occupation ratio (0.60-0.40)
- Stage 3: Severe atrophy Occupation ratio (<0.40)

Tangent sign:

Drawing a line from the superior border of the scapular spine to the superior margin of the coracoid process makes the tangent line. In a normal supraspinatus muscle, the muscle content should cross superior to the tangent line and is a negative tangent sign. When the muscle atrophies, the supraspinatus falls below the tangent line and is a positive tangent sign.



Negative Zanetti sign Positive Zanetti sign

WESTERN ONTARIO ROTATOR CUFF INDEX (WORC)©

Svensk version©
Swedish version

Ett diagnos-specifikt verktyg för att utvärdera livskvalitet hos personer med rotator cuff problem.(skulderbesvär).

PATIENTDATA

Namn: _____

Datum:____-____-____ Personnummer:_____-_____

Höger axel ☐ Vänster axel ☐ Högerhänt ☐ Vänsterhänt ☐

Version 2006-03-15

INSTRUKTIONER:

I de följande frågorna ombeds Du att besvara frågorna på följande sätt. Genom att markera med ett streck / på den horisontella linjen visar du hur du upplever din situation:

EXEMPEL:

1. Om Du sätter ett streck / längst till vänster på linjen visar Du att Du inte har någon smärta.

Ingen smärta Extremt svår smärta

2. Om Du sätter ett streck / längst till höger på linjen visar Du att Du har extremt svår smärta.

Ingen smärta Extremt svår smärta

Var vänlig observera:

a) att ju längre åt höger Du sätter ditt streck / desto ***mer*** upplever Du besväret.

b) att ju längre åt vänster Du sätter ditt streck / desto ***mindre*** upplever Du besväret.

c) placera inte ditt streck / utanför ändmarkeringarna.

Du är ombedd att markera på detta frågeformulär, till ***vilken grad*** Du har upplevt ett besvär kopplat till Din axel den ***senaste veckan***.

Om Du är osäker angående den aktuella axeln eller om Du har andra frågor, var då vänlig och fråga innan Du fyller i formuläret.

Om Du av någon anledning inte förstår en fråga **läs då först förklaringarna** som finns i slutet av formuläret. Därefter kan Du markera med ett / på den horisontella linjen.

Om en fråga inte gäller Dig eller om Du inte har upplevt dessa besvär under den senaste veckan försök i stället uppskatta vilket svar som passar bäst.

2

DEL A: FRÅGOR OM FYSISKA SYMPTOM

Patientinstruktioner:
De följande frågorna rör fysiska symptom, som Du eventuellt har upplevt på grund av Dina axelproblem. Var vänlig markera den grad av symptom Du upplevt under den ***senaste veckan***. Förklaringar finns i slutet av formuläret om du är osäker på frågan. (Var vänlig markera Dina svar med ett streck **/** på den horisontella linjen)

FRÅGOR:

1. **Hur mycket skärande smärta upplever Du i Din axel?**

Ingen smärta — Extrem smärta

2. **Hur mycket konstant, molande värk har Du i Din axel?**

Ingen värk — Extrem värk

3. **Hur svag upplever Du att Din axel är?**

Ingen svaghet — Extremt svag

4. **Hur stel eller rörelseinskränkt upplever Du att Din axel är?**

Inte stel — Extremt stel

5. **Hur mycket besväras Du av knäppande, skavande och knastrande i Din axel?**

Inte alls — Extremt mycket

6. Hur mycket obehag upplever Du i nackmuskulaturen p g a Din axel?

Inget alls Extremt mycket

DEL B: FRÅGOR OM SPORT/FRITID

Patientinstruktioner:
Den följande delen handlar om hur Dina axelproblem påverkat sport- eller fritidsaktiviteter under den ***senaste veckan***. Förklaringar finns i slutet av formuläret om du är osäker på frågan.
(Var vänlig markera Dina svar med ett streck / på den horisontella linjen)

FRÅGOR:

7. Hur mycket har Din axel påverkat Din fysiska form?
Inte alls Extremt mycket

8. Hur svårt upplever Du p g a Din axel att göra armhävningar eller andra övningar som anstränger axeln?

Inte svårt Extremt svårt

9. Hur mycket har Din axel påverkat Din förmåga att kasta något kraftfullt eller långt?

Inte påverkat Påverkat extremt

10. Hur stor svårighet har Du när någon eller någonting kommer i kontakt med Din sjuka axel?

Ingen svårighet Extrem svårighet

DEL C: FRÅGOR OM ARBETE

Patientinstruktioner:
Den följande delen handlar om hur Dina axelproblem har påverkat Ditt arbete i eller utanför hemmet. Svara med avseende på hur du påverkats den ***senaste veckan***.
Förklaringar finns i slutet av formuläret om du är osäker på frågan.
(Var vänlig markera Dina svar med ett streck / på den horisontella linjen)

FRÅGOR:

11. Hur stora svårigheter upplever Du i dagliga aktiviteter i hemmet eller i trädgården?

Inga svårigheter — Extrema svårigheter

12. Hur stora svårigheter har Du att arbeta ovan axelhöjd?

Inga svårigheter — Extrema svårigheter

13. Hur mycket använder Du Din friskare arm för att kompensera för Din sjuka arm?

Inte alls — Ständigt

14. Hur stor svårighet upplever Du att lyfta tunga föremål under och upp till axelhöjd?

Ingen svårighet — Extrem svårighet

5

DEL D: FRÅGOR OM LIVSSTIL

Patientinstruktioner:
Den följande delen handlar om i vilken utsträckning Dina axelproblem har påverkat eller förändrat Din livsstil. Svara med avseende på hur du påverkats den ***senaste veckan***.
Förklaringar finns i slutet av formuläret om du är osäker på frågan.
(Var vänlig markera Dina svar med ett streck **/** på den horisontella linjen)

FRÅGOR:

15. Hur stor svårighet har Du att sova p g a Din axel?

Ingen svårighet — Extrem svårighet

16. Hur stor svårighet har Du att sköta håret p g a Din axel?

Ingen svårighet — Extrem svårighet

17. Hur svårt upplever Du det är att ”härja runt eller busa” med familj eller vänner?

Ingen svårighet — Extrem svårighet

18. Hur stor svårighet har Du att klä på eller av Dig?

Ingen svårighet — Extremt svårighet

DEL E: FRÅGOR OM KÄNSLOR

Patientinstruktioner:
De följande frågorna berör hur Du har känt Dig den ***senaste veckan*** med hänsyn till Dina skulderproblem. Förklaringar finns i slutet av formuläret om du är osäker på frågan. (Var vänlig markera Dina svar med ett streck / på den horisontella linjen)

FRÅGOR:

19. Hur frustrerad känner Du Dig p g a Din axel?

Inte alls Extremt mycket

20. Hur ”nedtryckt i skorna” eller nedstämd känner Du Dig p g a axeln?

Inte alls Extremt mycket

21. Hur oroad eller bekymrad är Du över hur axeln kan påverka Ditt arbete?

Inte alls Extremt oroad

Tack för att Du besvarat alla frågorna !

7

om en hälsning klappar Dig på axeln.

8

tanför hemmet!).

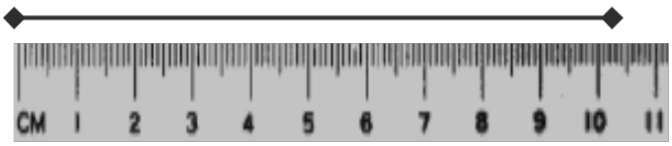
9

TILL DIG SOM DELAR UT WORC TILL PATIENTERNA:

Denna och sista sidan avskiljes och behöver inte lämnas till patienterna.

Den linje som frågorna skall besvaras på skall alltid vara 100 mm lång.

Kontrollmät här att linjen har rätt längd, eller klipp av detta papper vid linjalen och använd den vid mätning:



Bäst är att alltid skriva ut formuläret från pdf-fil vilket minskar risken att dator och skrivare har inställningar som ändrar längden.

(Även när formuläret kopieras i kopiator kan längden i värsta fall ändras)

Suggested citation:
The development and evaluation of a disease-specific quality of life measurement tool for rotator cuff disease: The Western Ontario Rotator cuff index, Clinical Journal of Sport Medicine 13(2):84-92, 2003.

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SAMMANRÄKNING AV WESTERN ONTARIO ROTATOR CUFF INDEX (WORC)

DENNA SIDA IFYLLES AV UNDERSÖKAREN

1 Mät avståndet från vänster kant av linjen till / -markeringen i millimeter (0-100), med mätnogrannhet i närmaste 0,5 mm.
Fyll i siffran på motsvarande rad nedan.

2 Man kan räkna samman en totalsumma för vardera avsnitt (Fysiska symptom 600, Sport / Fritid 400, Arbete 400, Livsstil 400, Känslor 300).
Och/eller en totalsumma för alla avsnitt med maximum 2100.
Det värsta tänkbara resultatet är 2100.

3 Om man vill kan man redovisa resultatet i procent av normal funktion.
Dra den uppnådda totalsumman ifrån 2100 och dela med 21.
100% = bästa resultat och normal funktion.
Exempel: Patientens totalsumma =1625, det procentuella resultatet blir då:
2100-1625 = 475, 475 / 21=22,62 d.v.s. 22,6%.
På samma sätt kan vardera avsnitts resultat beräknas som procent.

Fysiska	Sport / Fritid	Arbete	Livsstil	Känslor	Total Summa
F1 ,	S7 ,	A11 ,	L15 ,	K19 ,	F ,
F2 ,	S8 ,	A12 ,	L16 ,	K20 ,	S ,
F3 ,	S9 ,	A13 ,	L17 ,	K21 ,	A ,
F4 ,	S10 ,	A14 ,	L18 ,	Summa ,	L ,
F5 ,	Summa ,	Summa ,	Summa ,		K ,
F6 ,				300- / 3	Summa ,
Summa ,	400- / 4	400- / 4	400- / 4	= %	2100- /21
600- / 6	= %	= %	= %		= %
= %					

NAMN: _____

(PERS-) NUMMER: _____

AXEL: HÖ ☐ VÄ ☐

DOM: HÖ ☐ VÄ ☐

DATUM: _____

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